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D'Souza et al.

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(54) **MASK SYSTEM**

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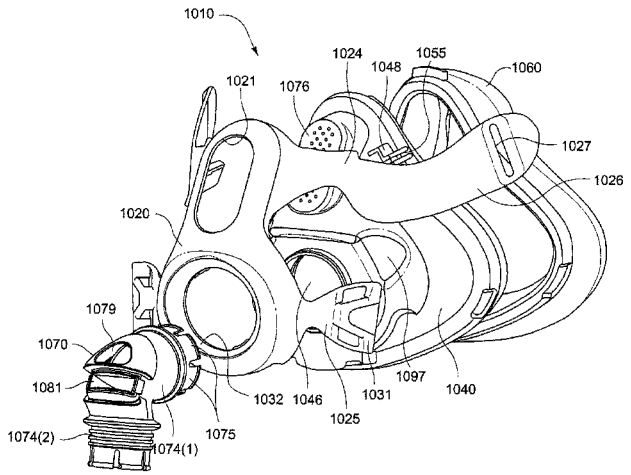
(57) **ABSTRACT**

A mask system has a shroud module with headgear connectors adapted to removably attach to respective headgear straps of headgear; and a cushion module, including a frame defining a breathing chamber; and a cushion to form a seal with the patient's face in a nasal bridge region, a cheek region and a lower lip/chin region of the patient's face. The cushion is constructed of a first, relatively soft, elastomeric material and the frame is constructed of a second material that is more rigid than the cushion, and a nasal bridge portion of the cushion includes one or more folds to provide in use a higher level of adaptability or flexibility to the nasal bridge region of the cushion module relative to another region of the cushion module. The shroud module and the cushion module are configured to be removably coupleable to one another.

79 Claims, 81 Drawing Sheets



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6 photos of ResMed S8 Escape flow generator tub and liner, the tub and liner are joined by a chemical bond resulting from co-moulding.

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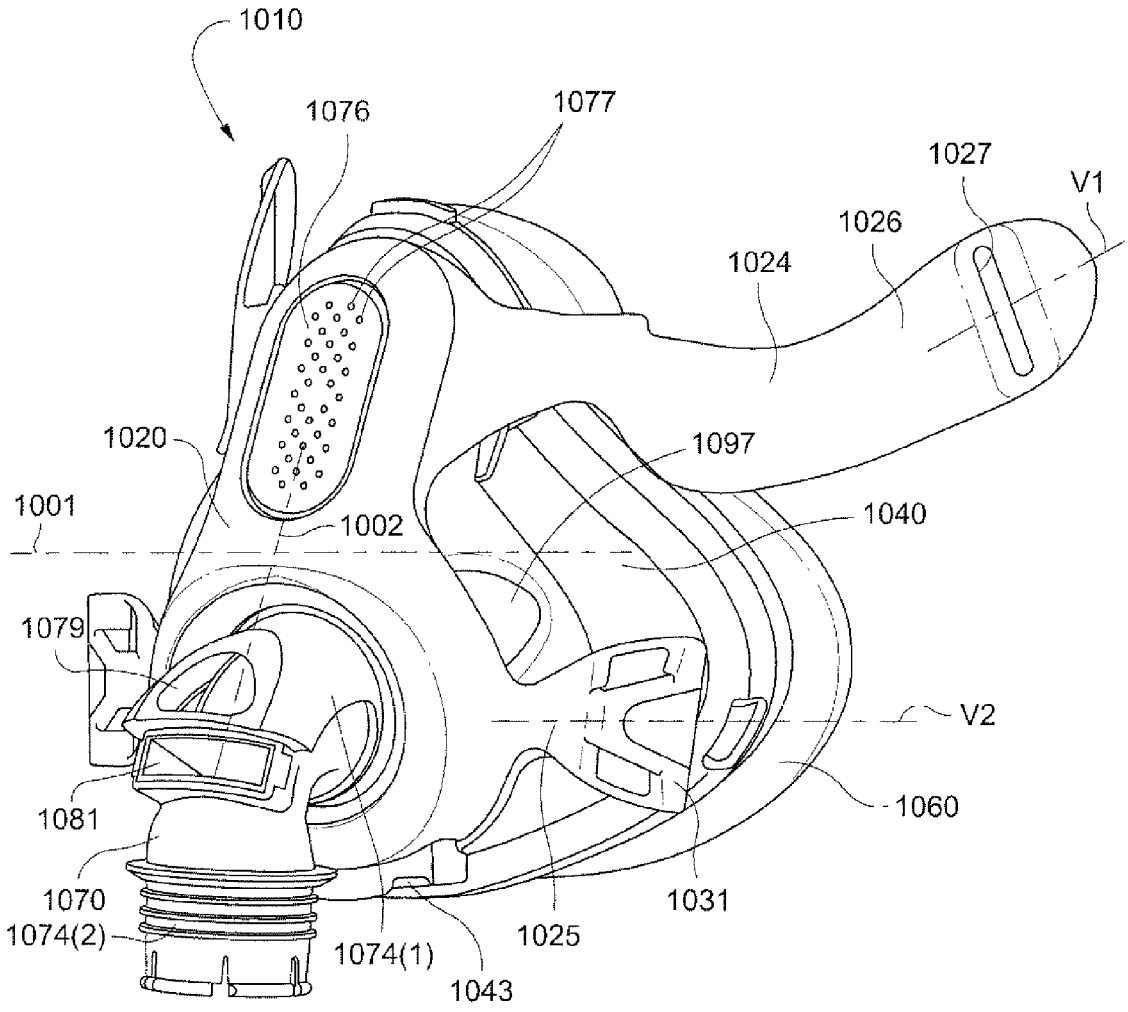
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Fig. 1

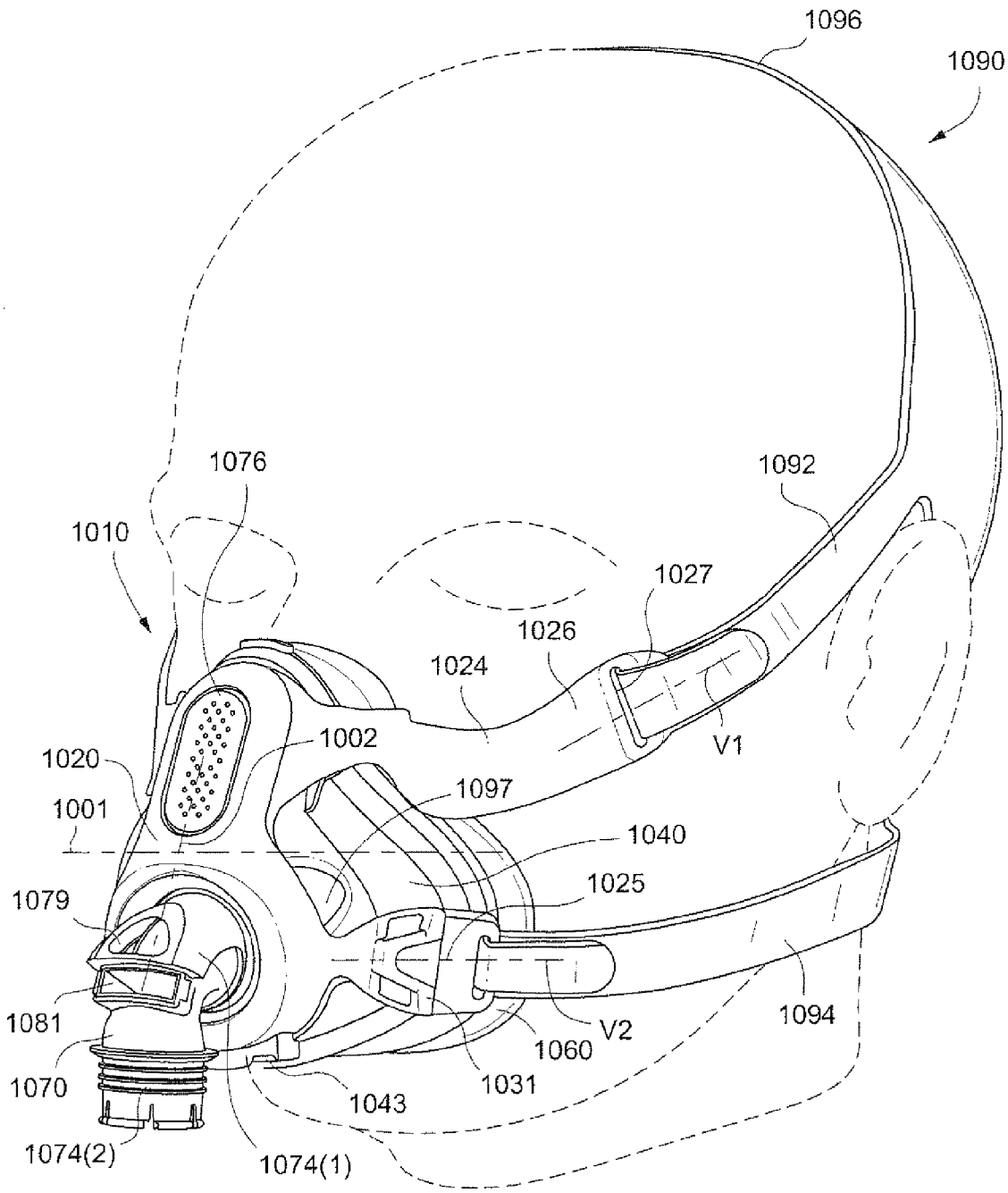
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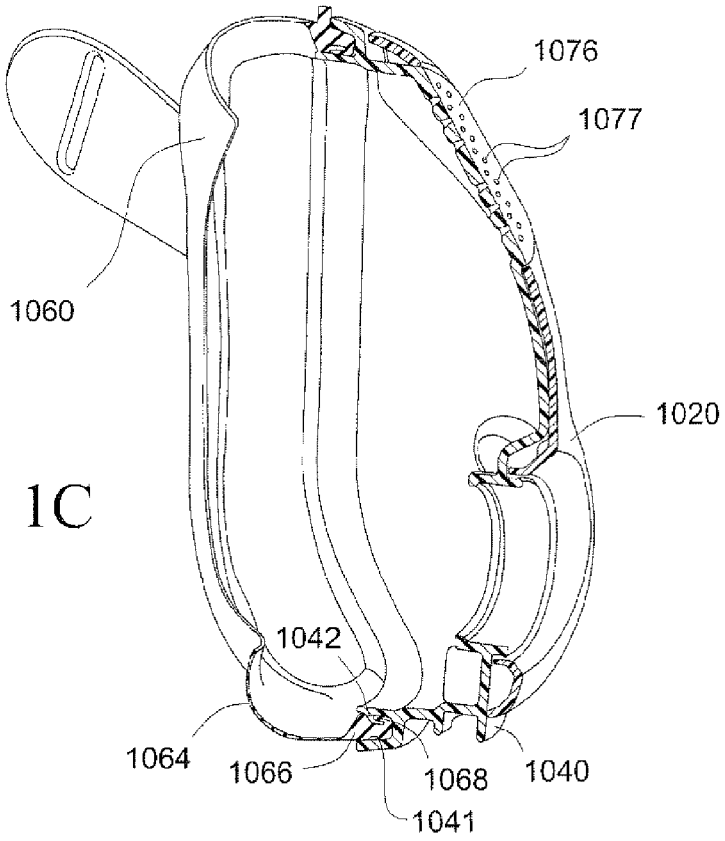
Fig. 1B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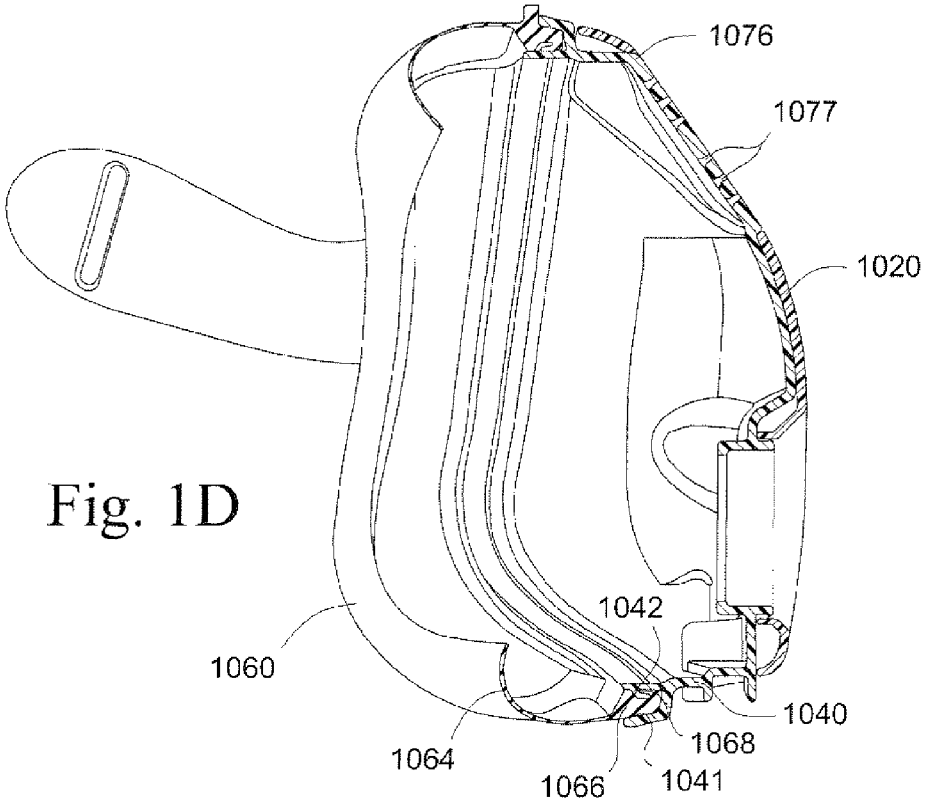
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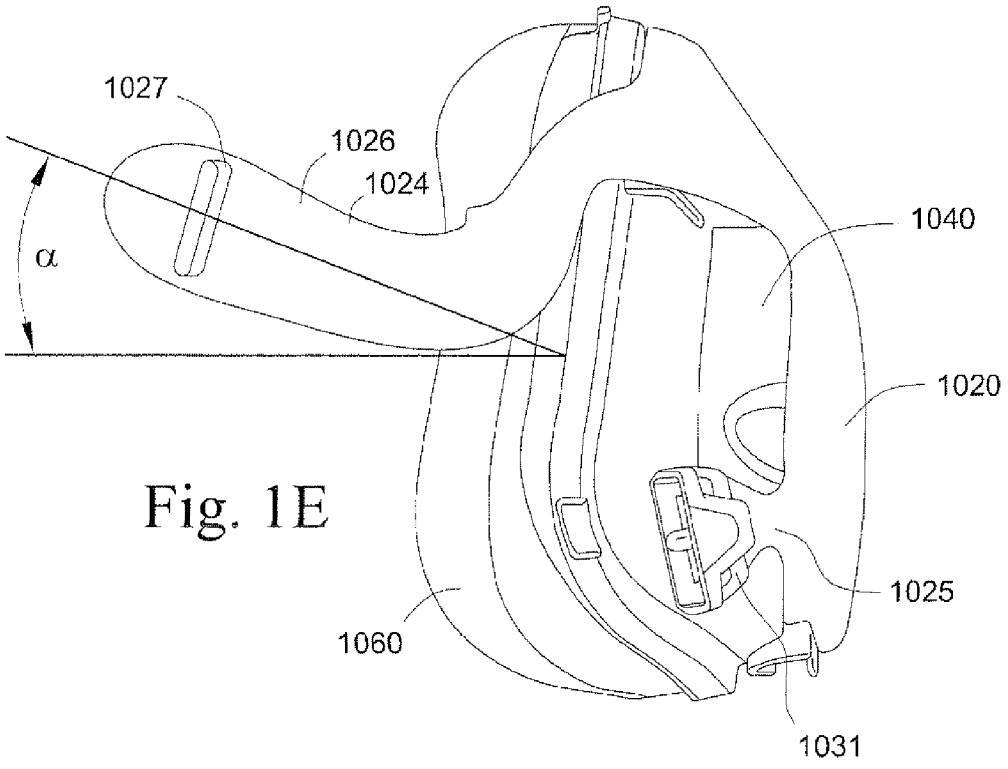

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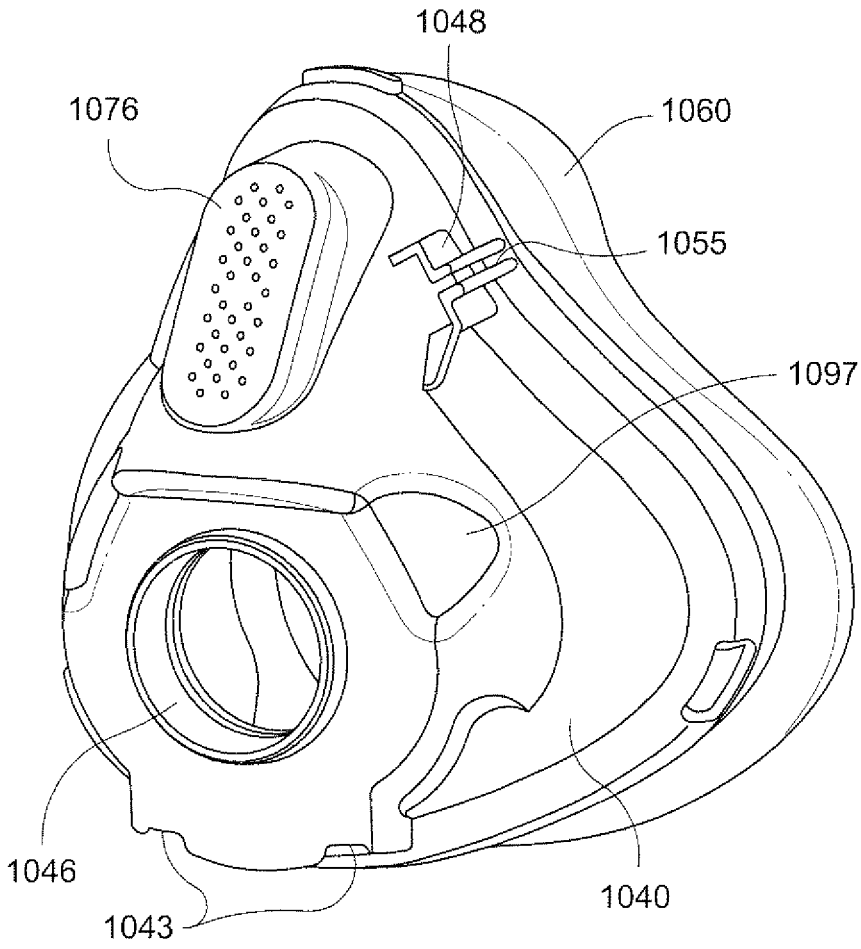

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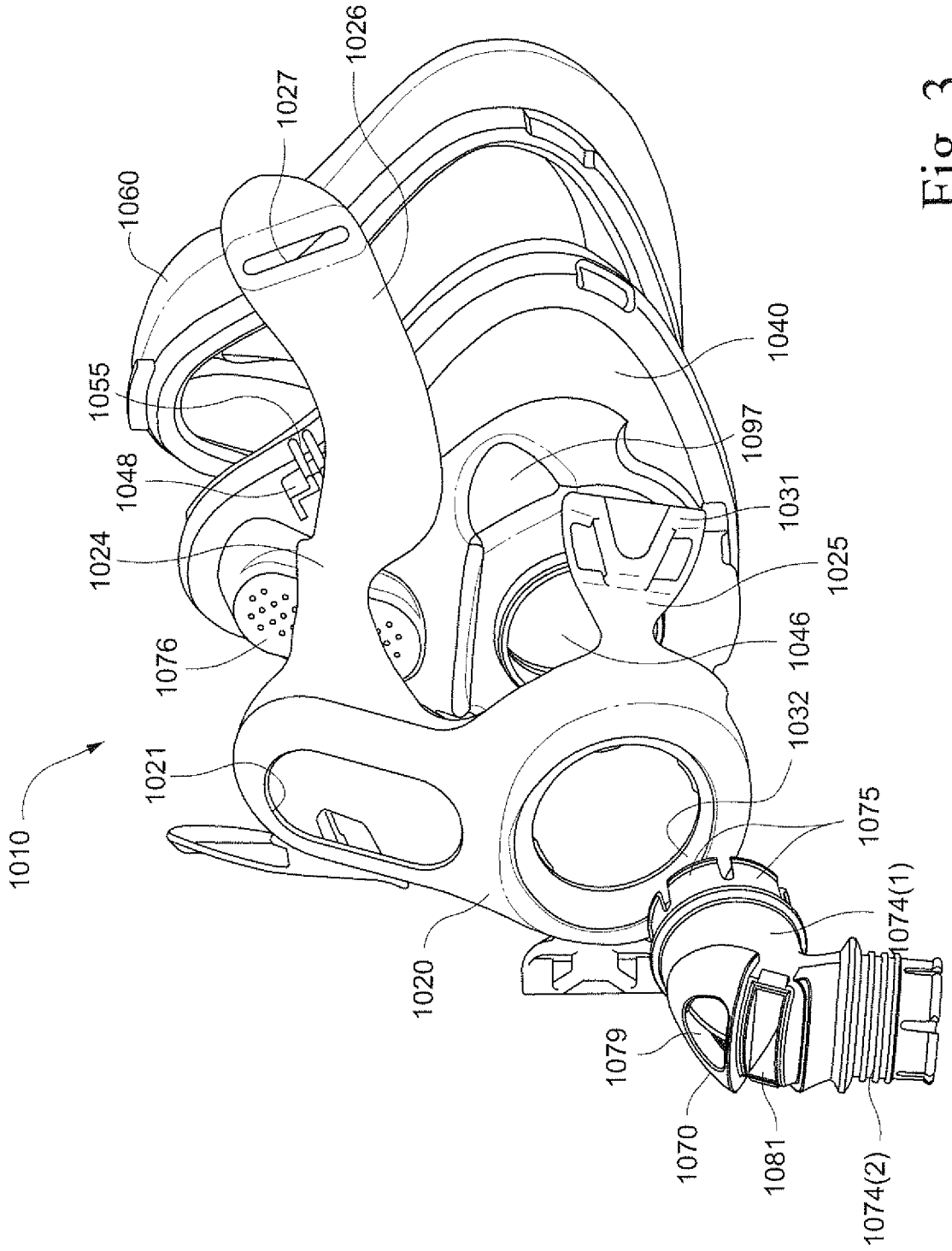
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Fig. 3

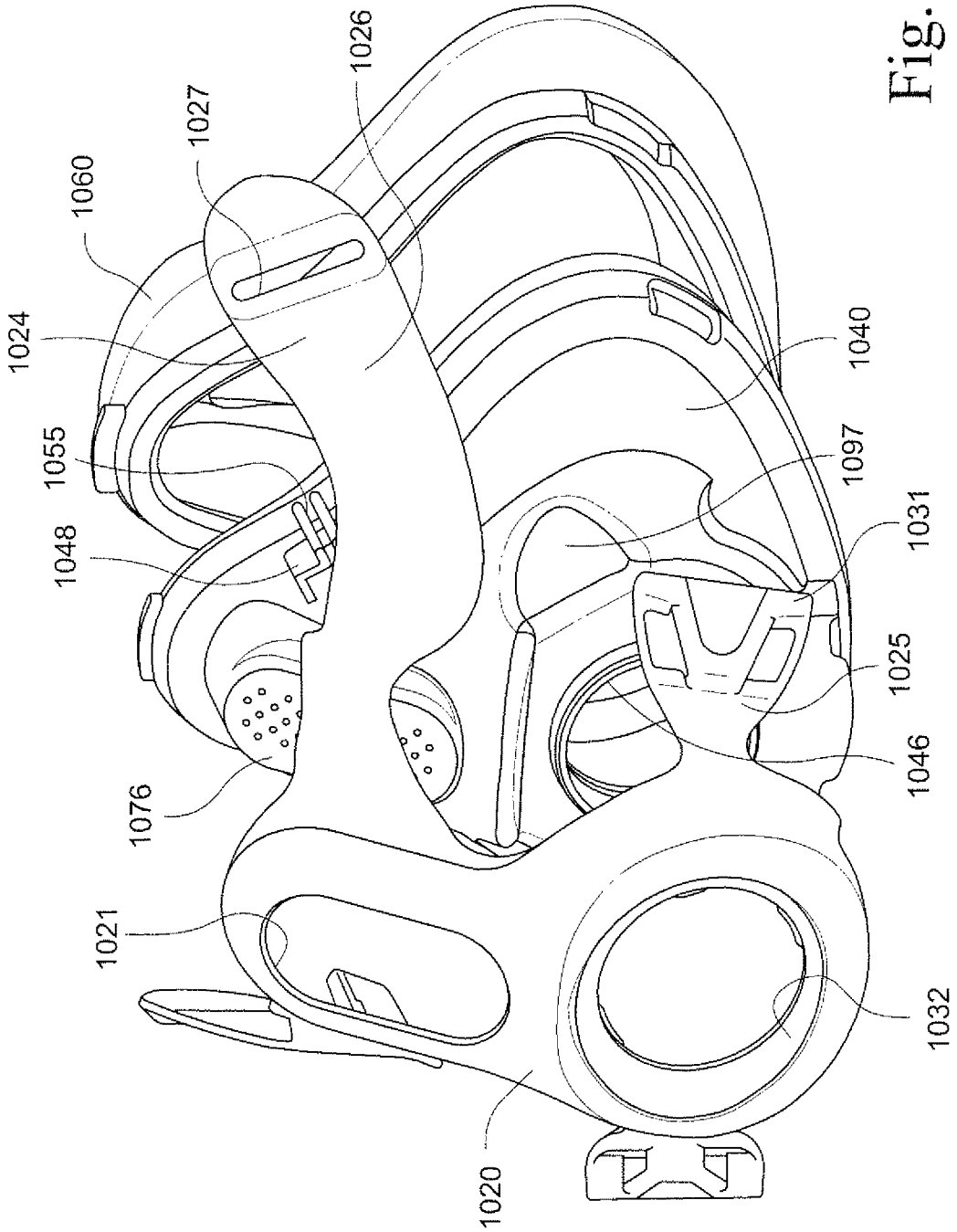
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Fig. 4

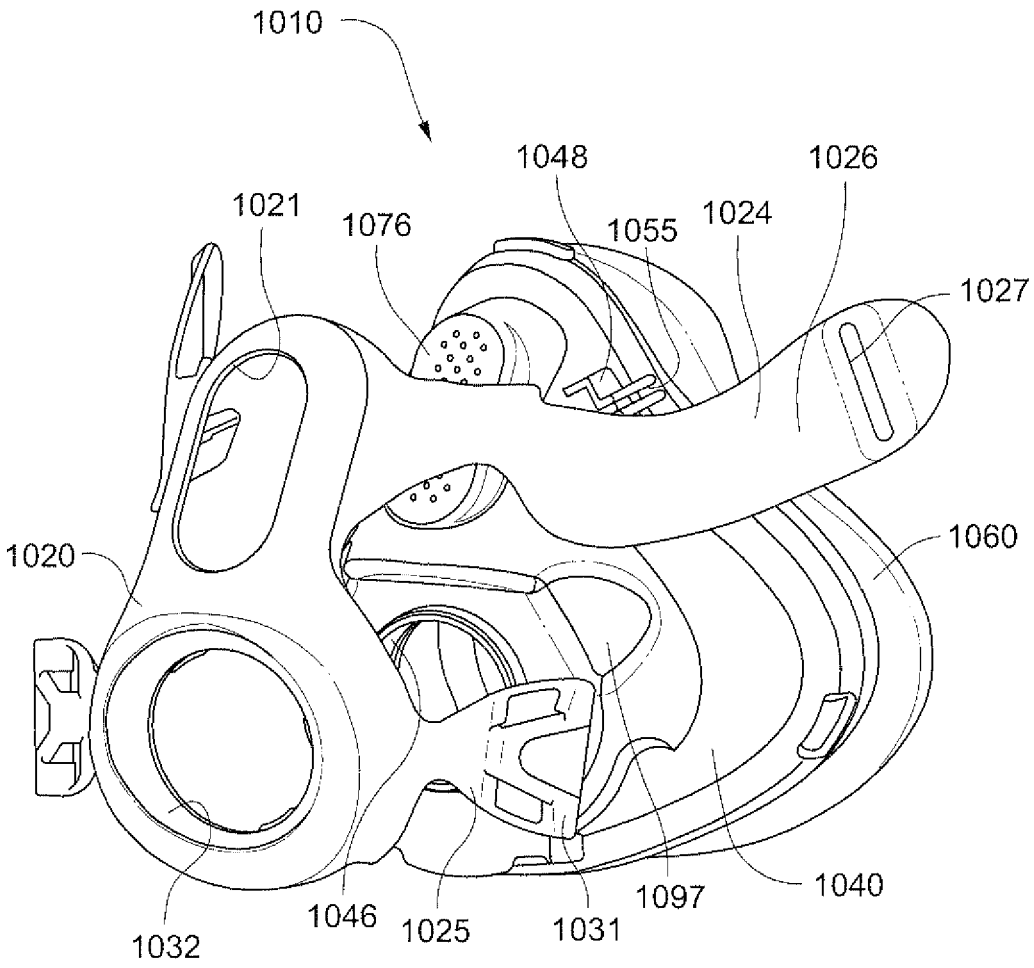
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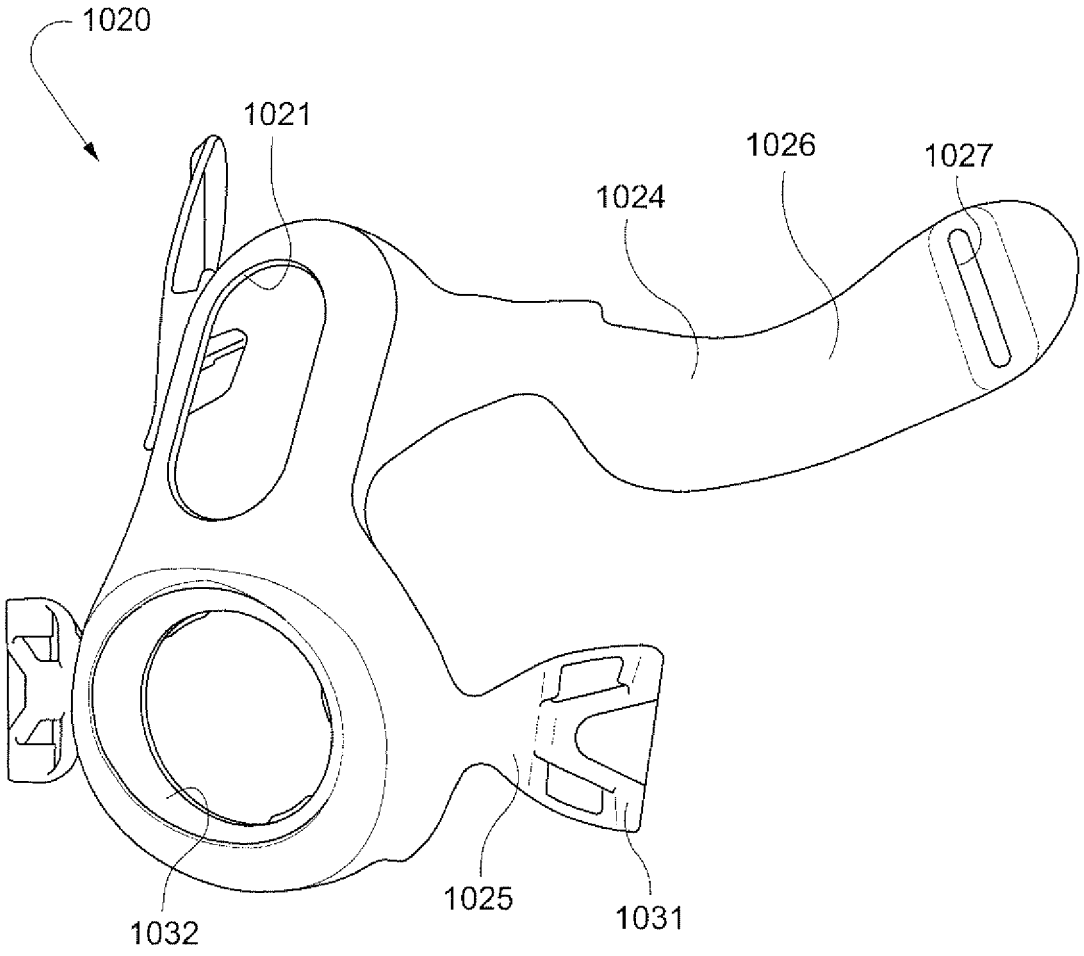
Fig. 5



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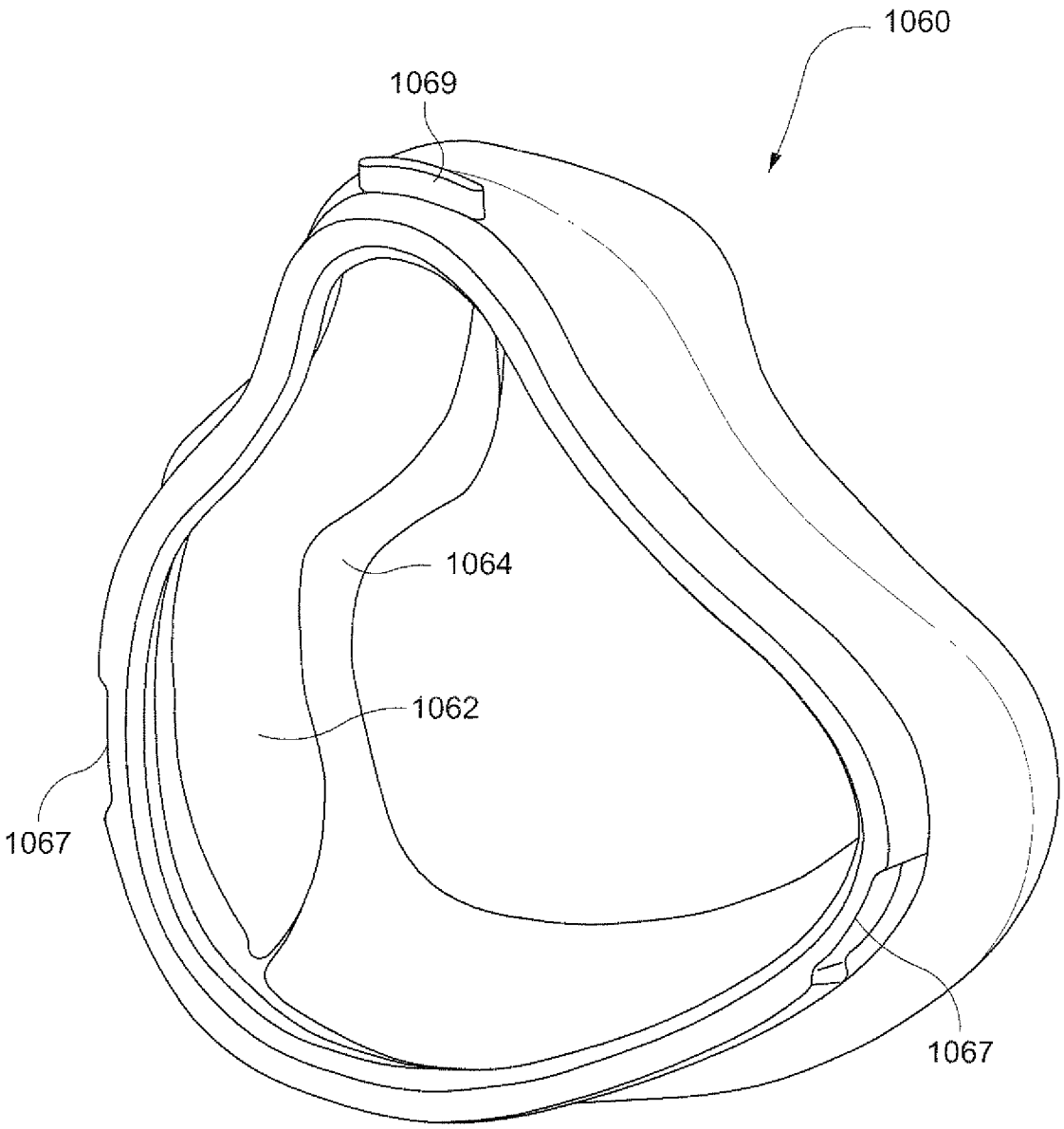

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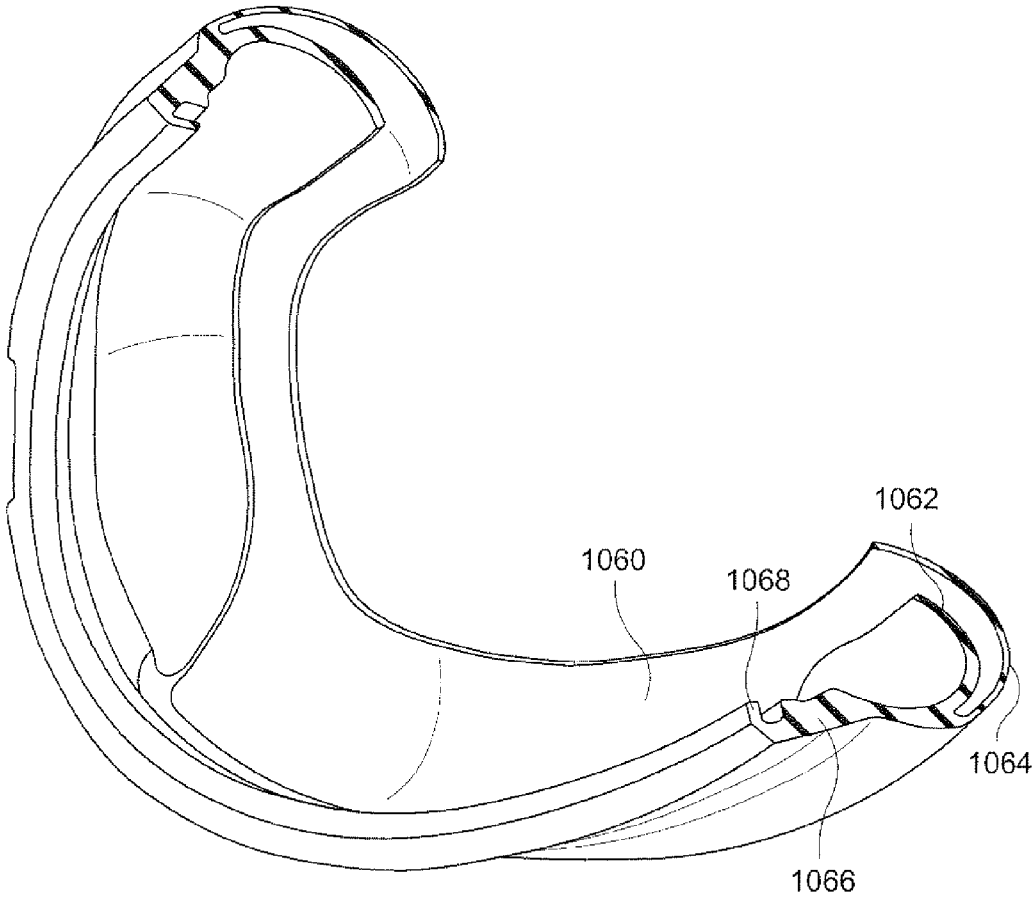

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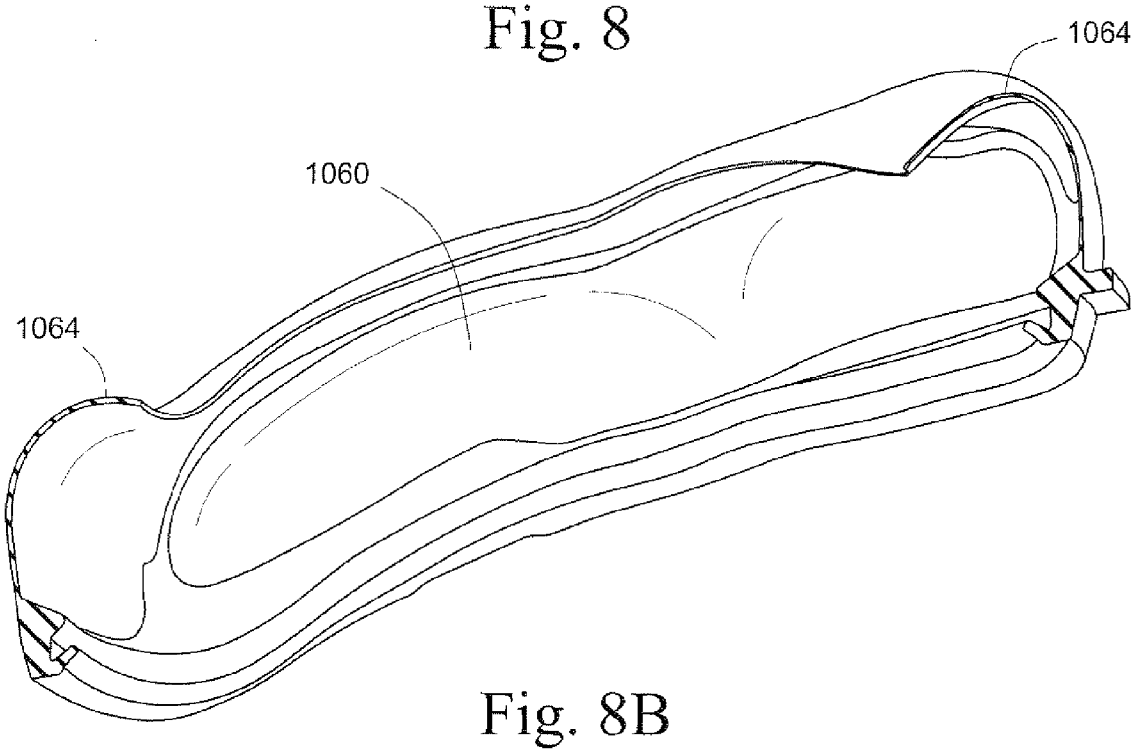

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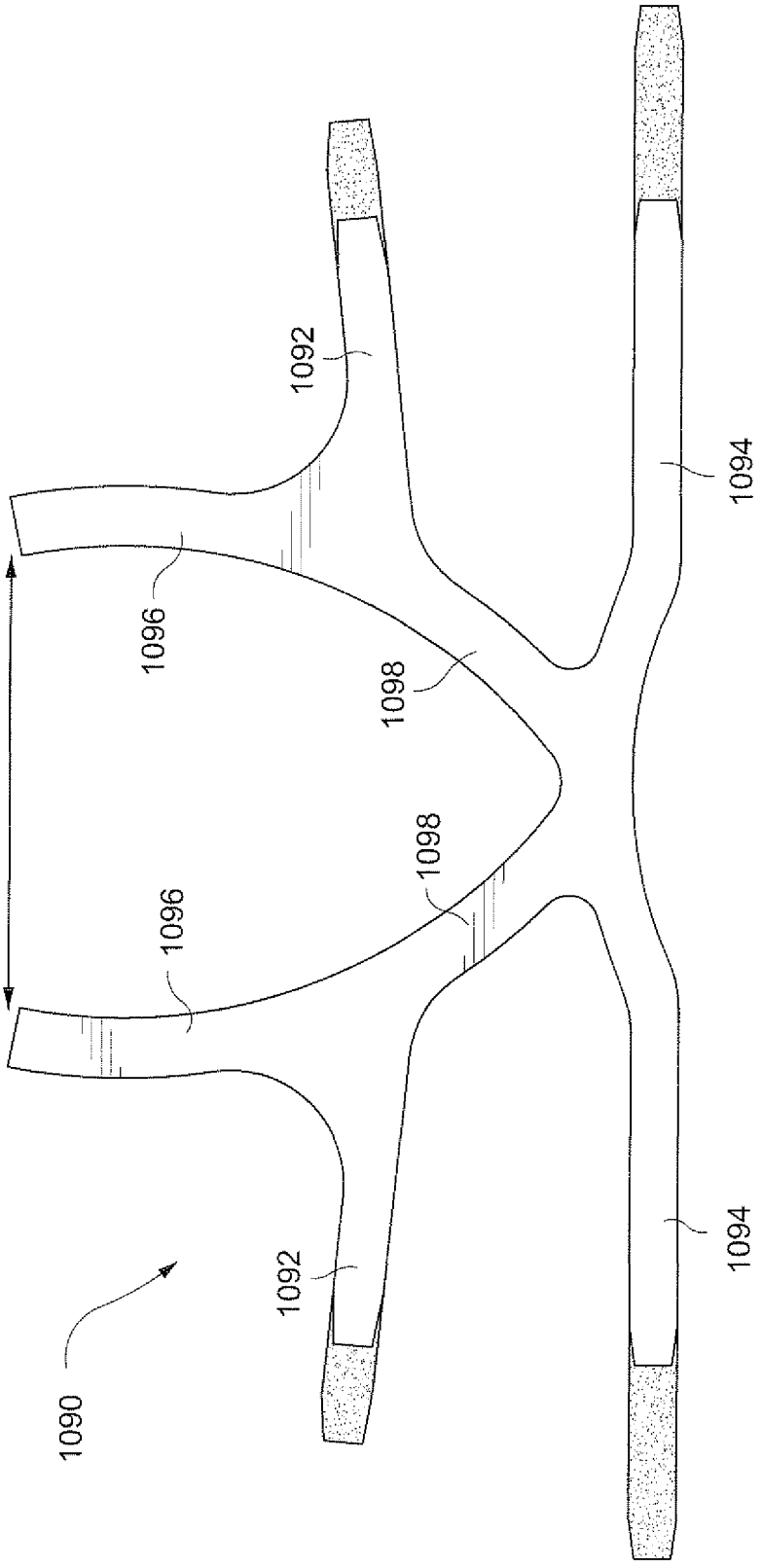

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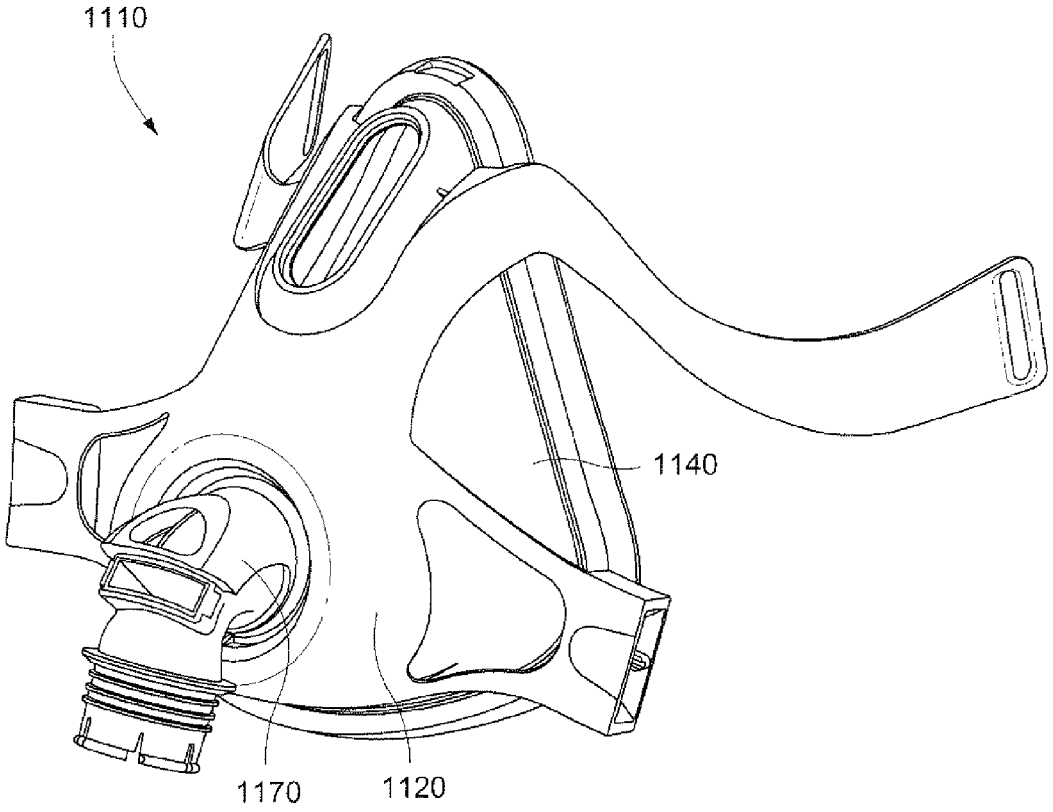

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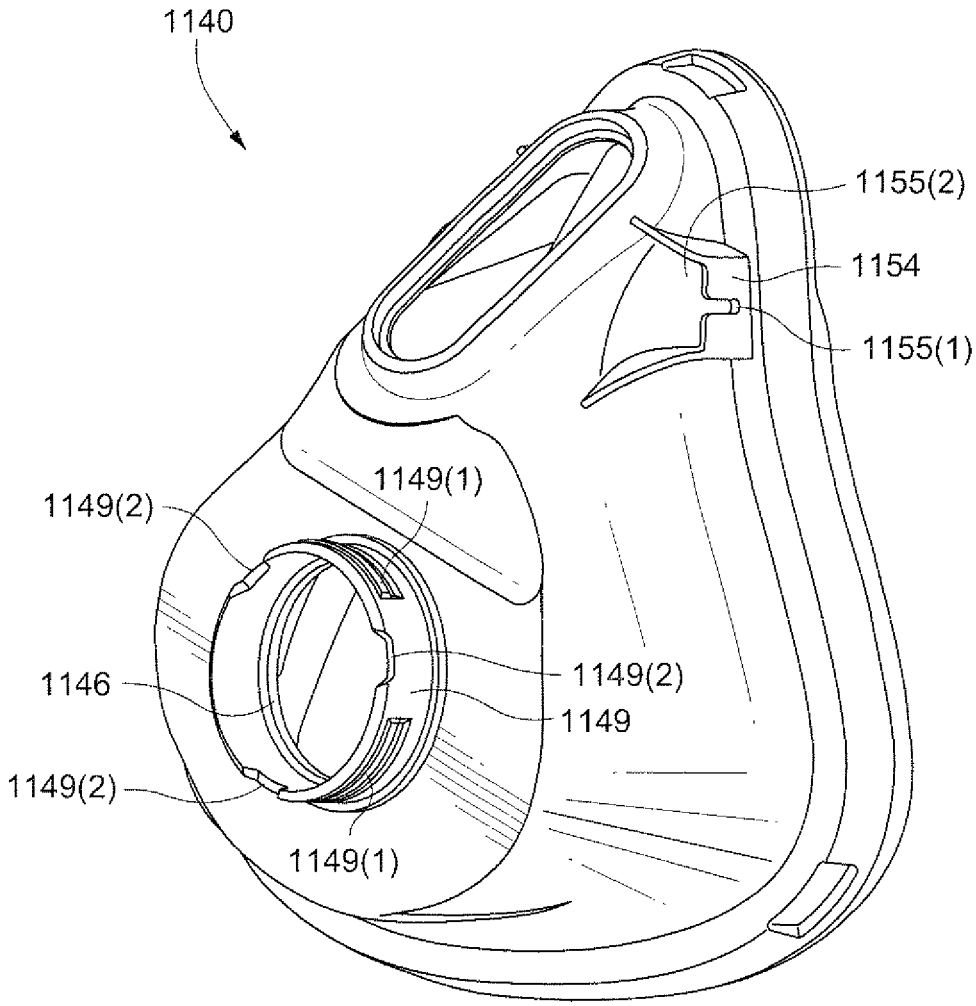
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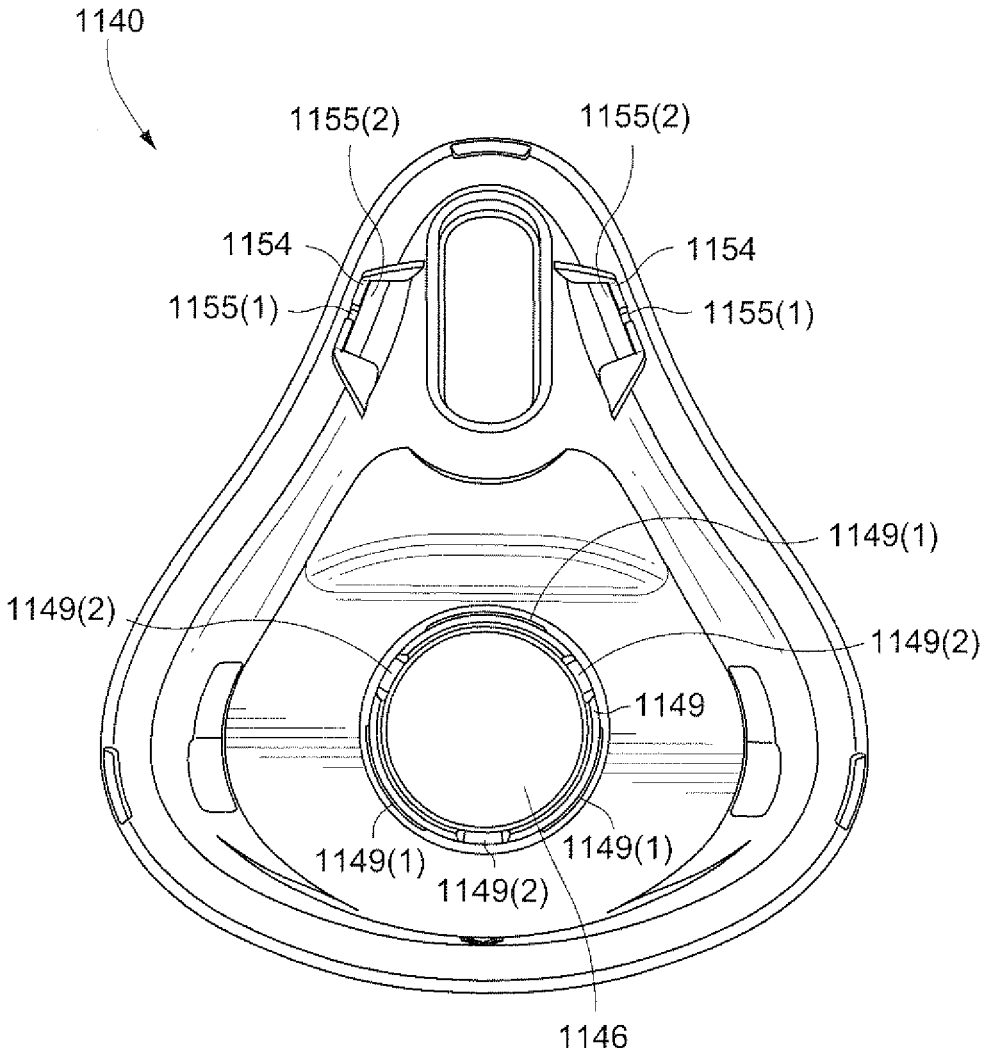
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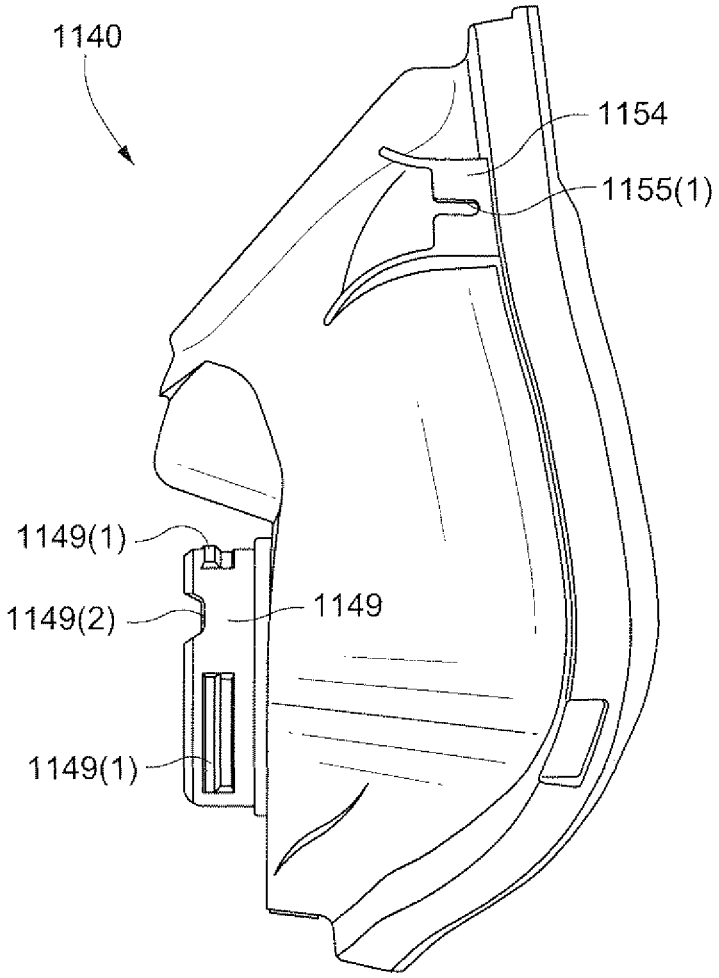
Fig. 12



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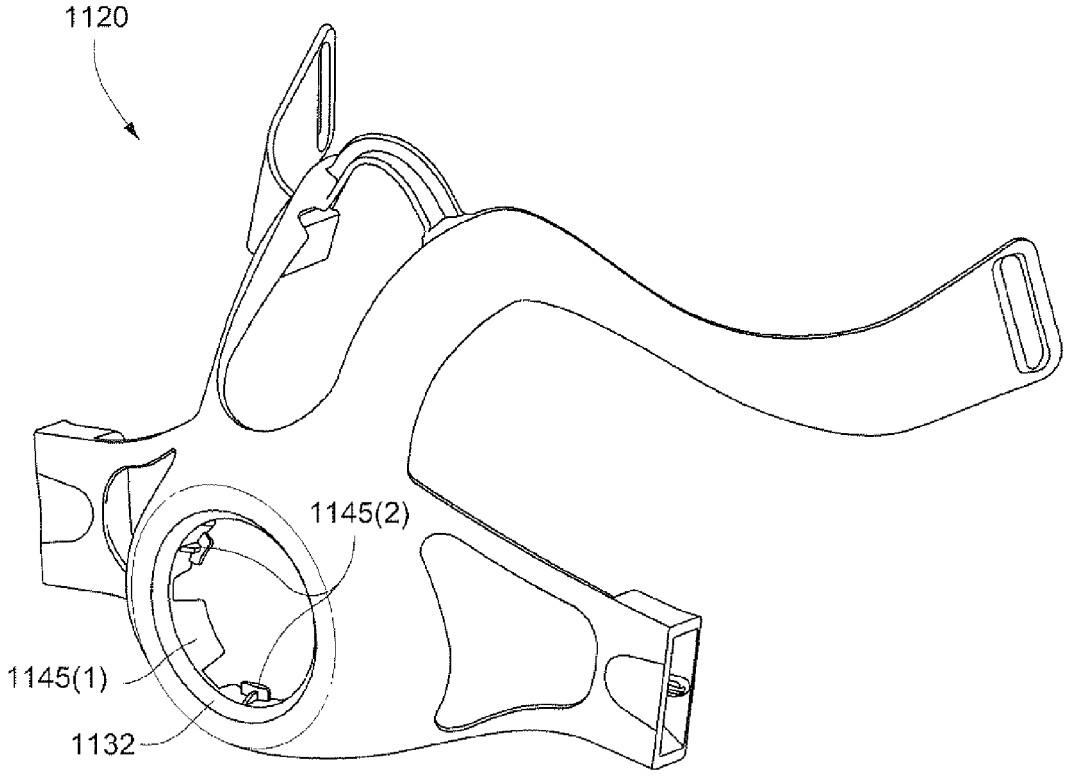

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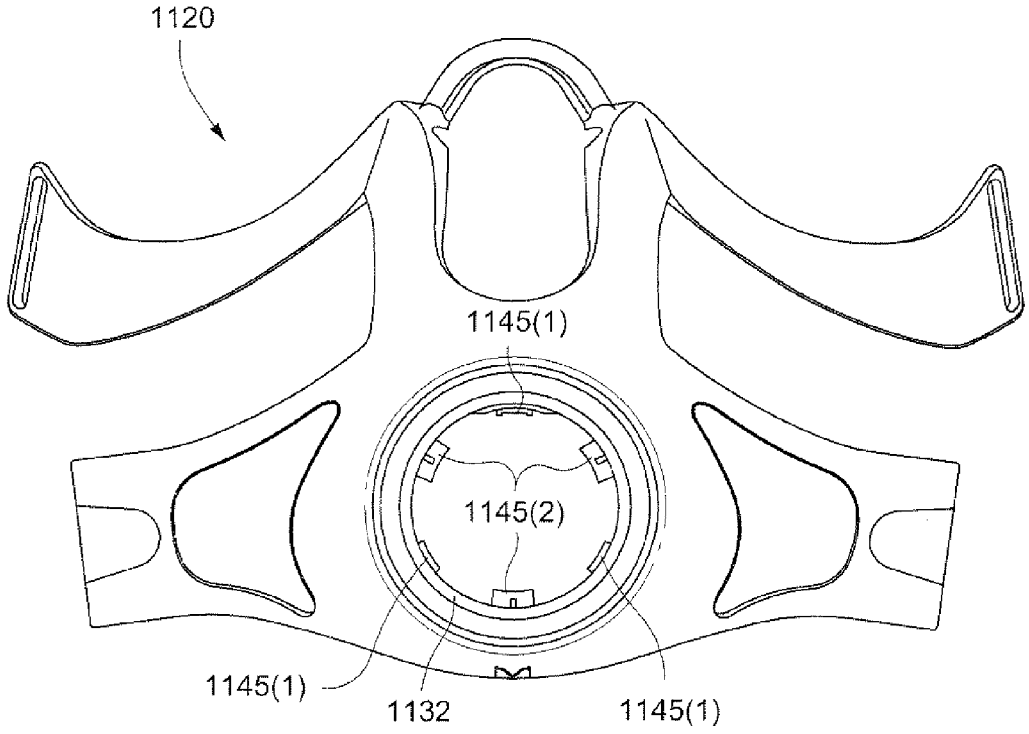

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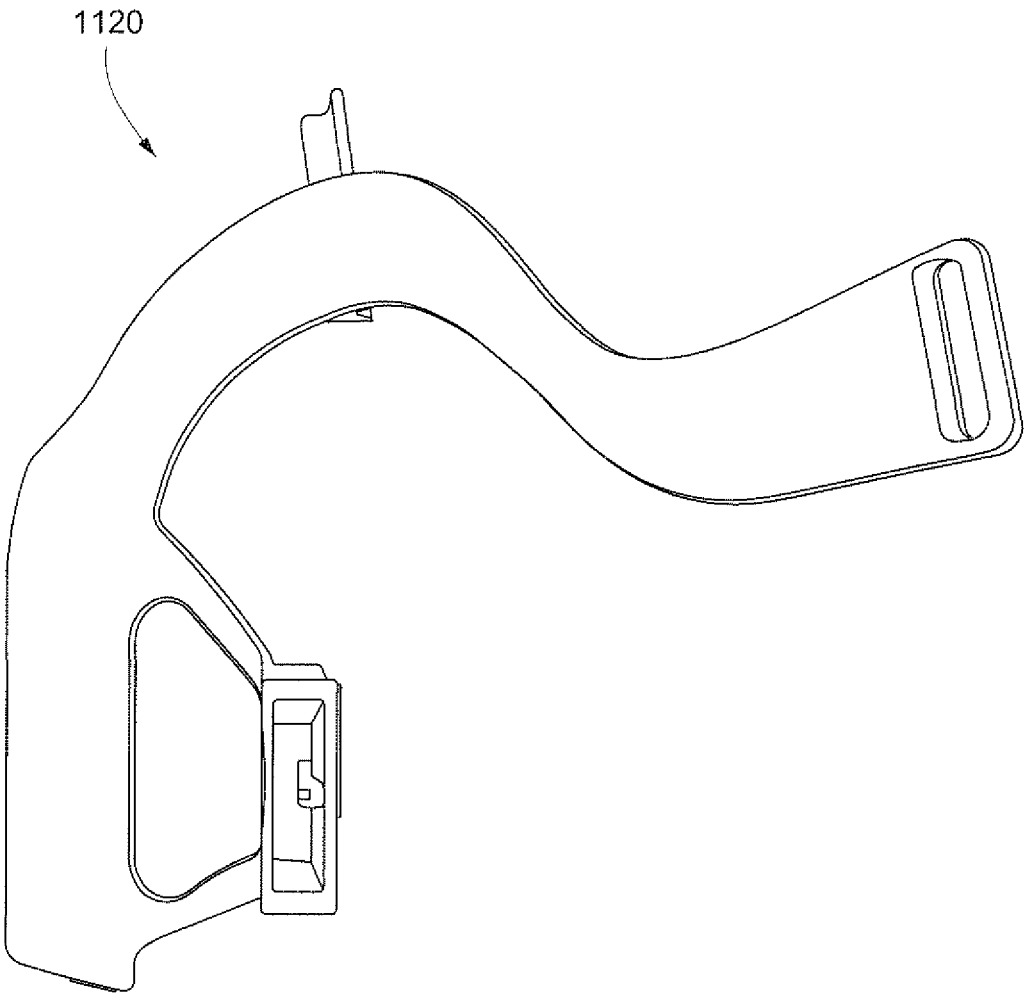

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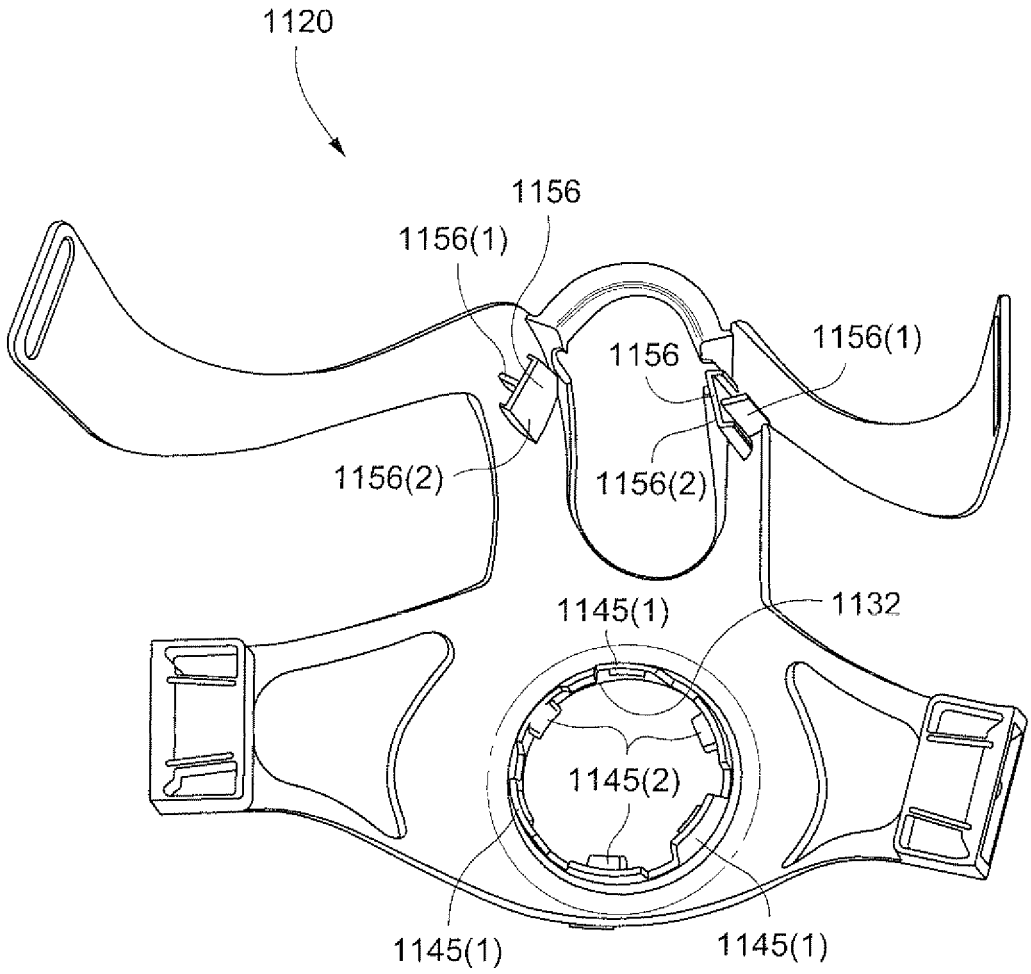
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Fig. 17

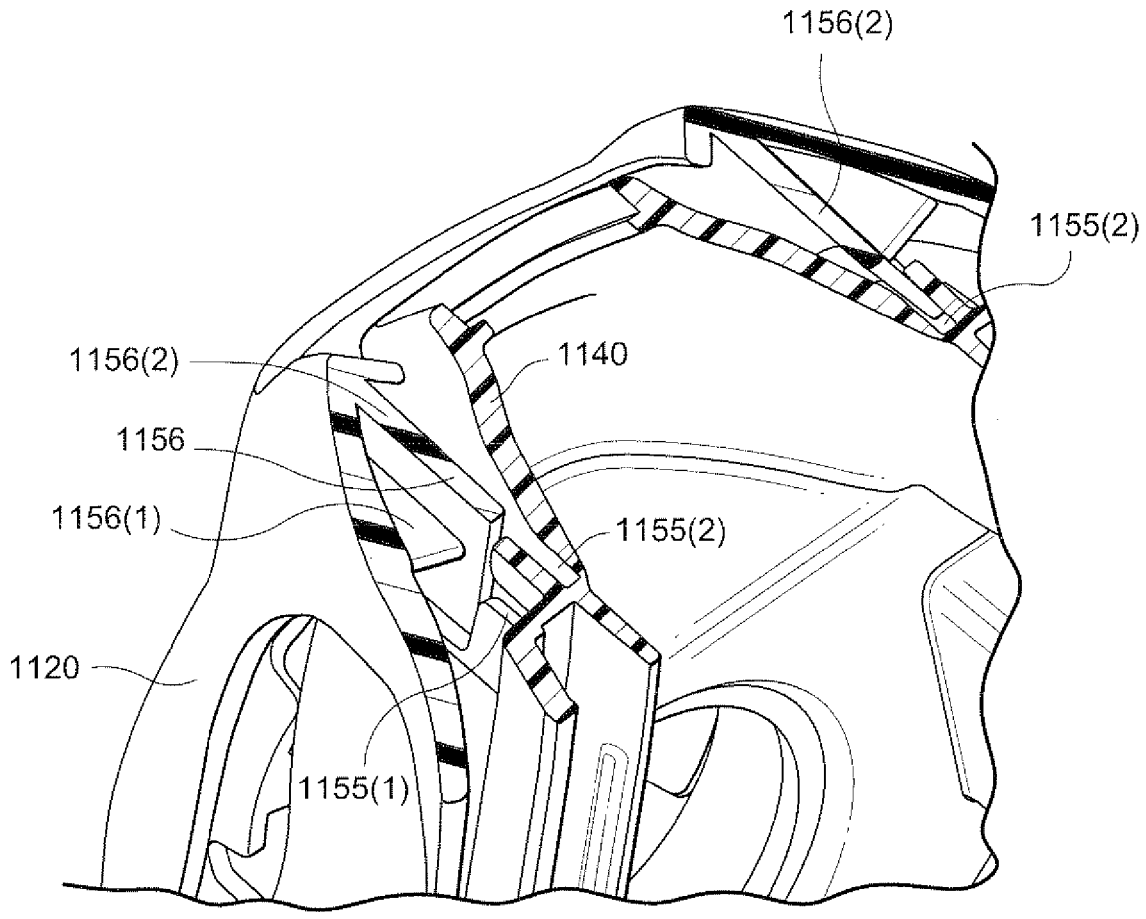


Fig. 18-1

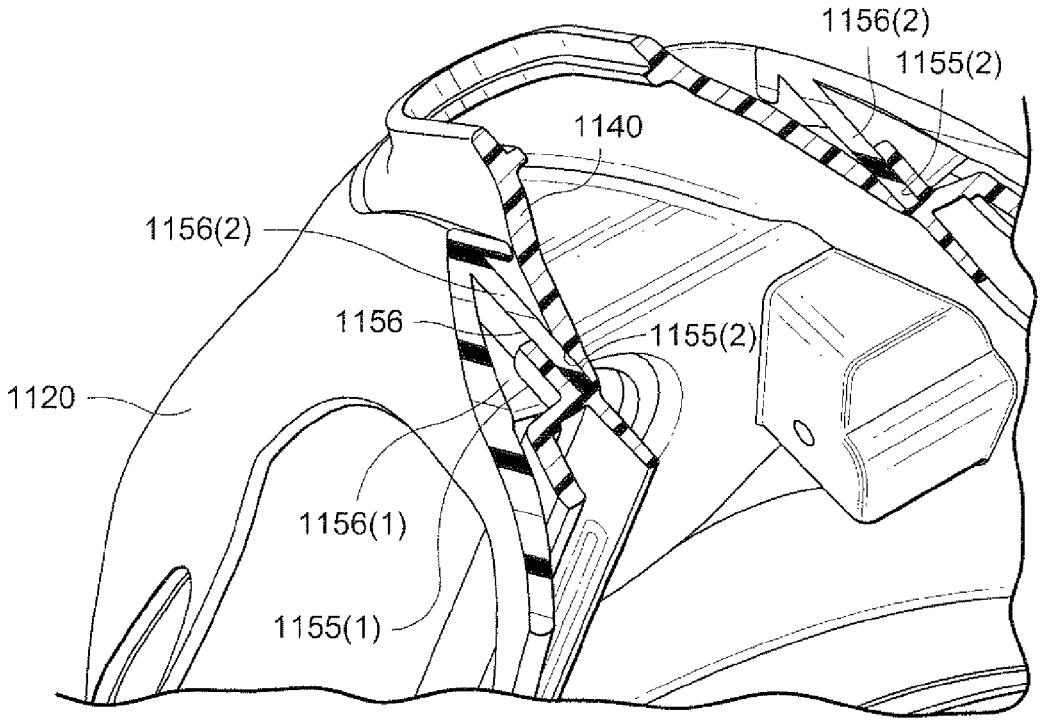
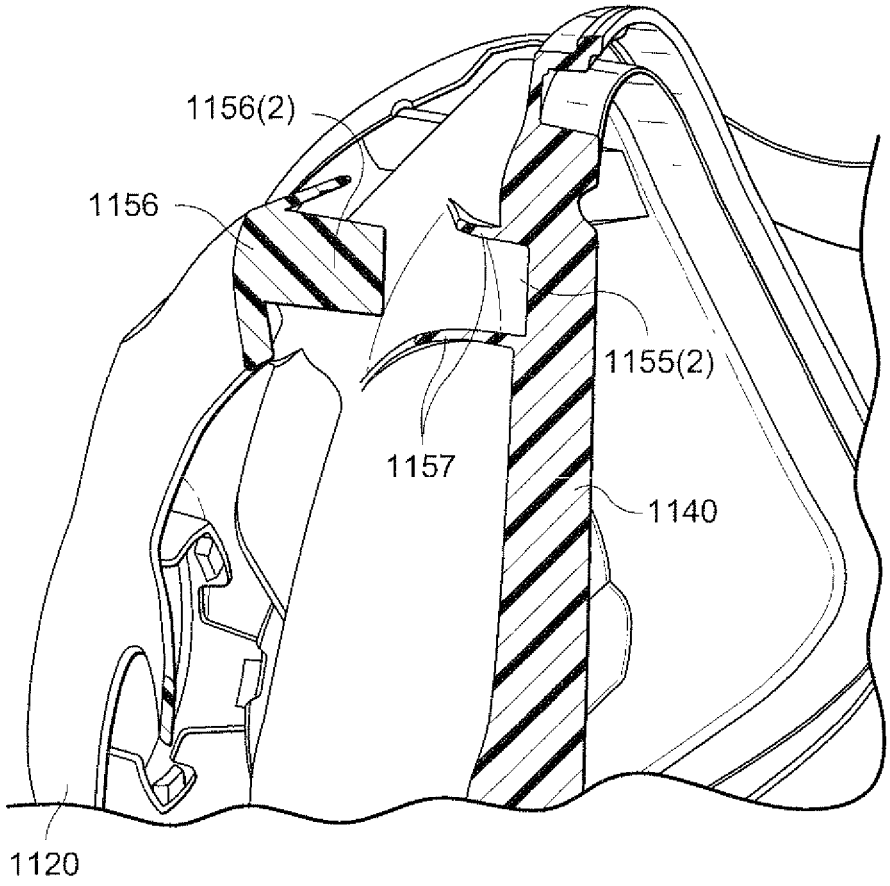


Fig. 18-2



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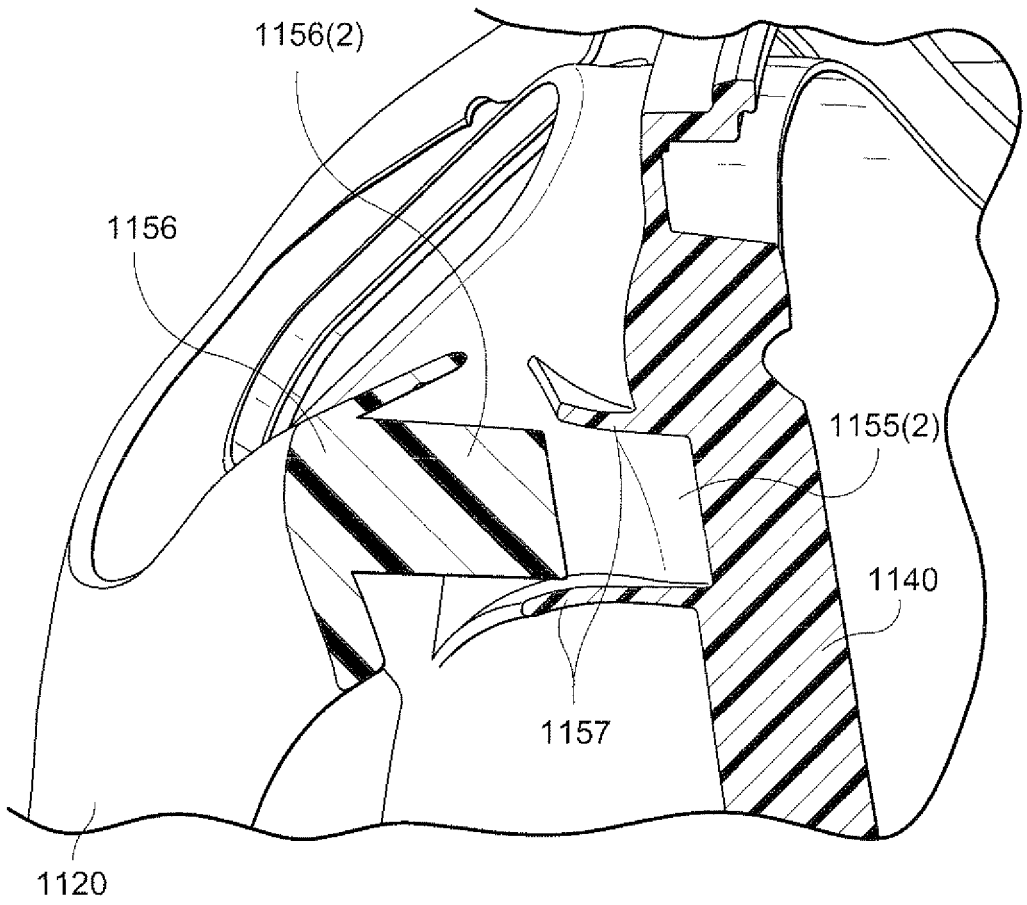

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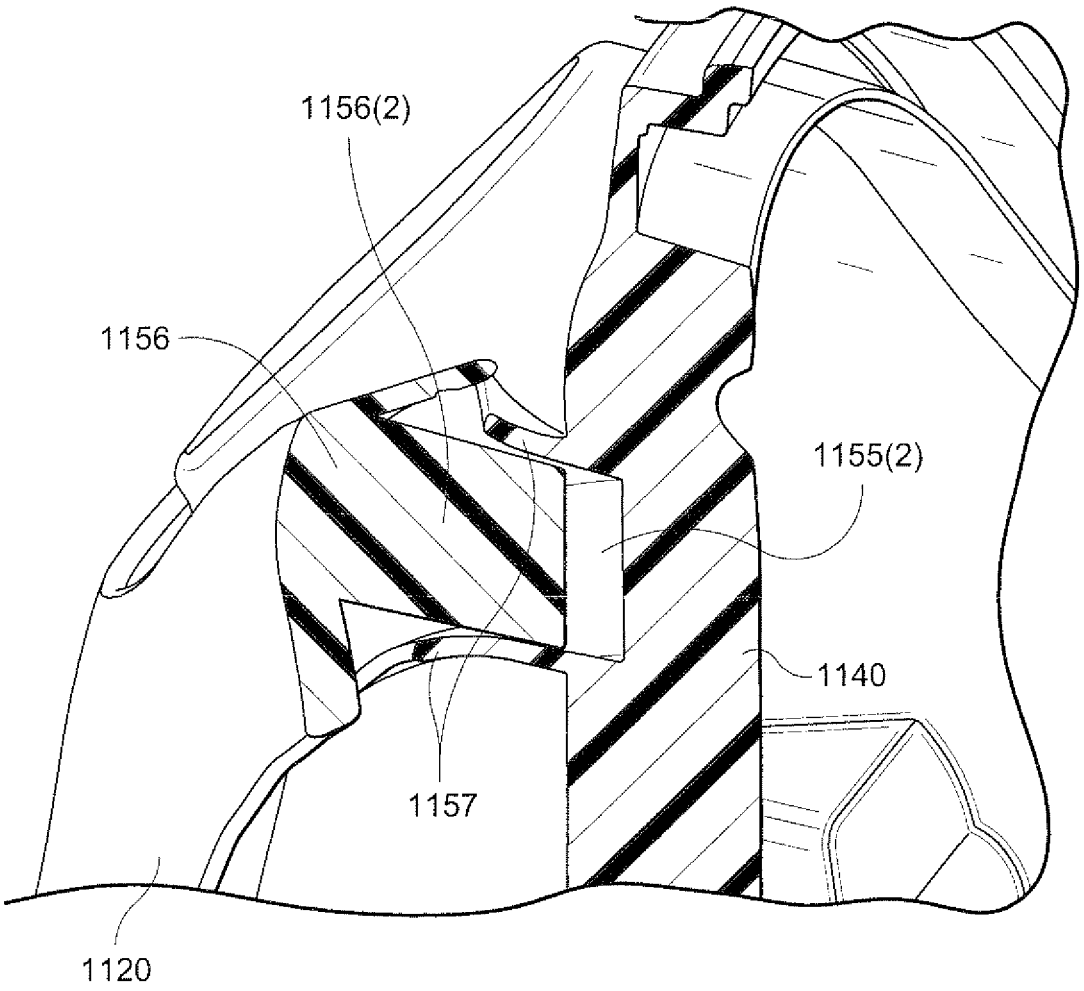
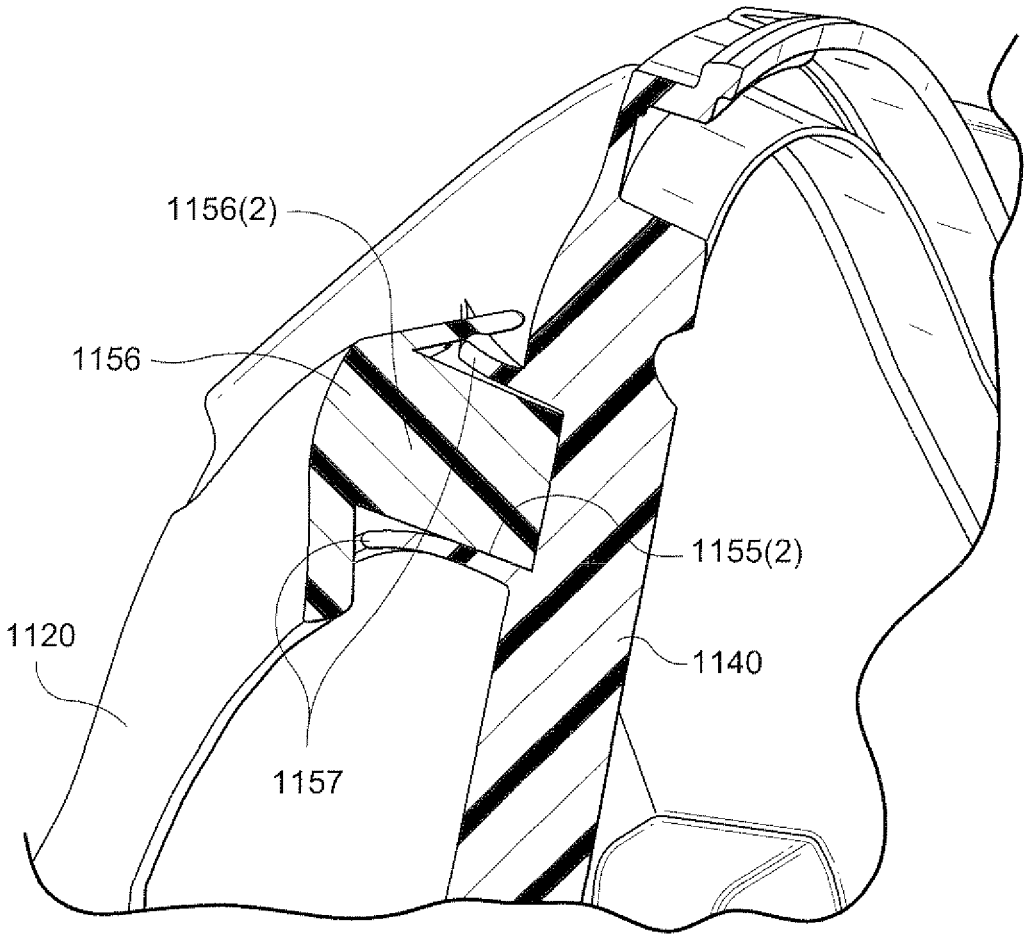


Fig. 19-3



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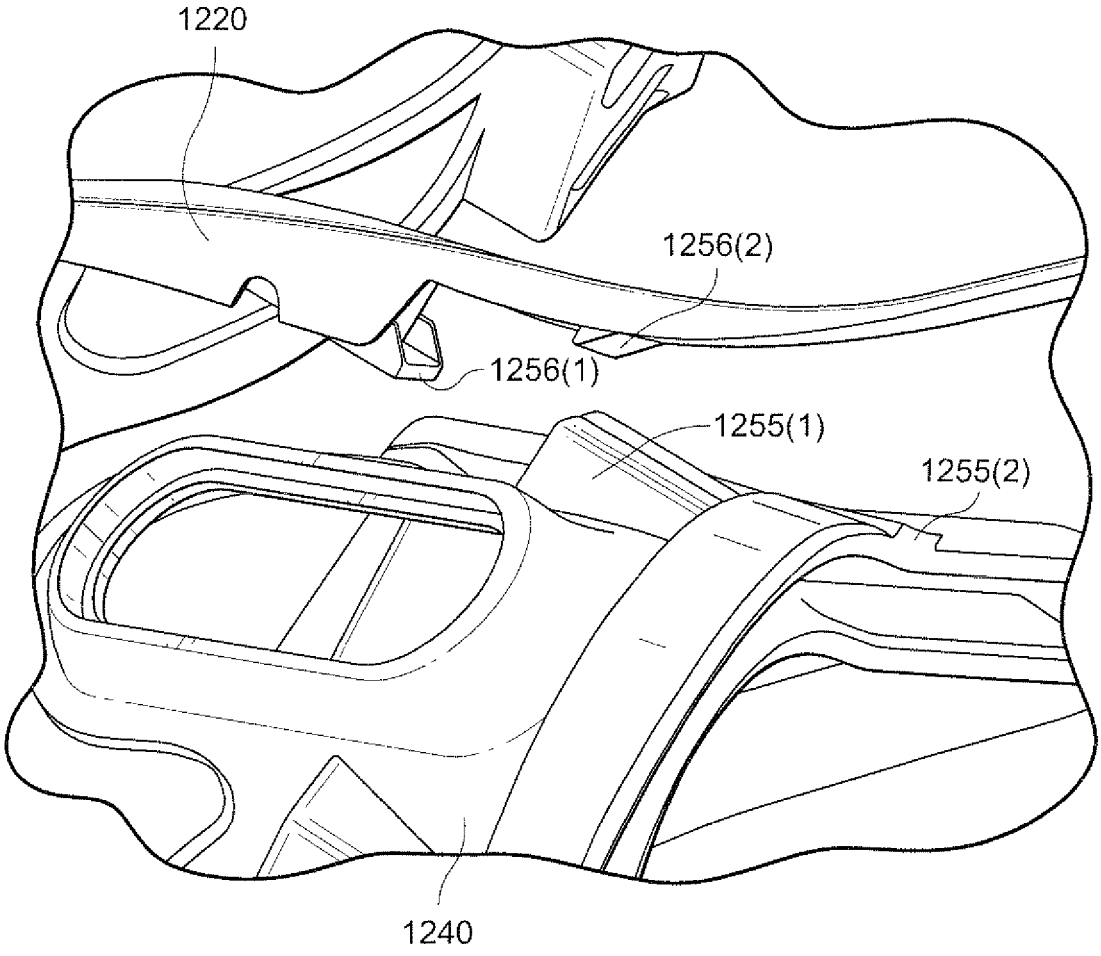

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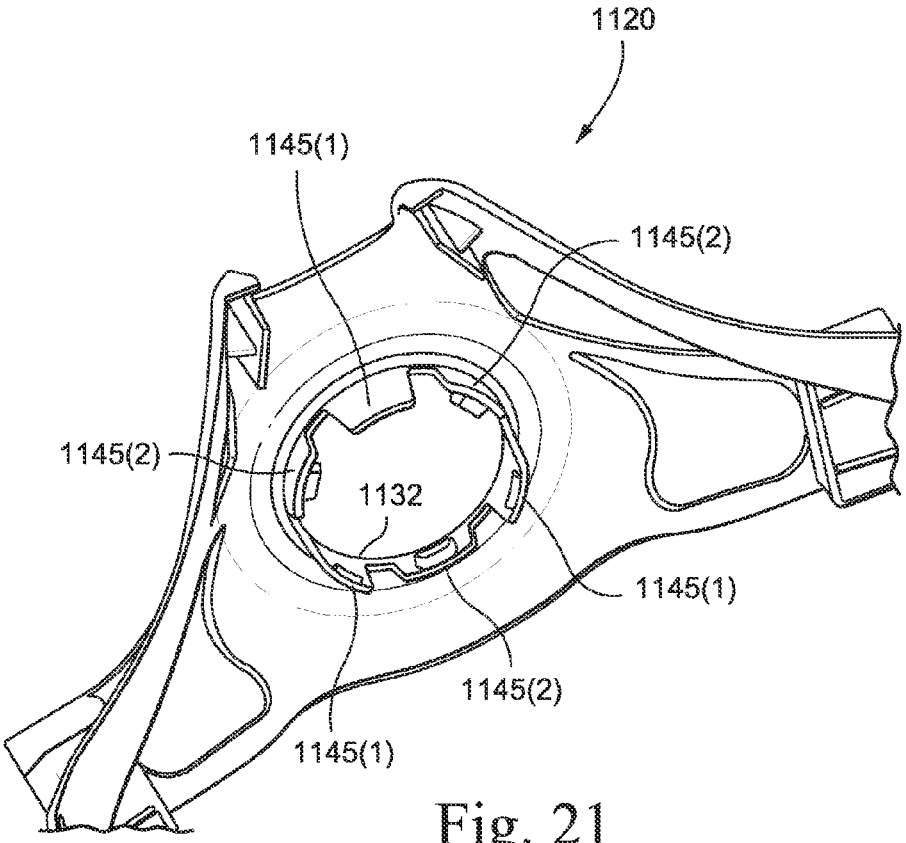
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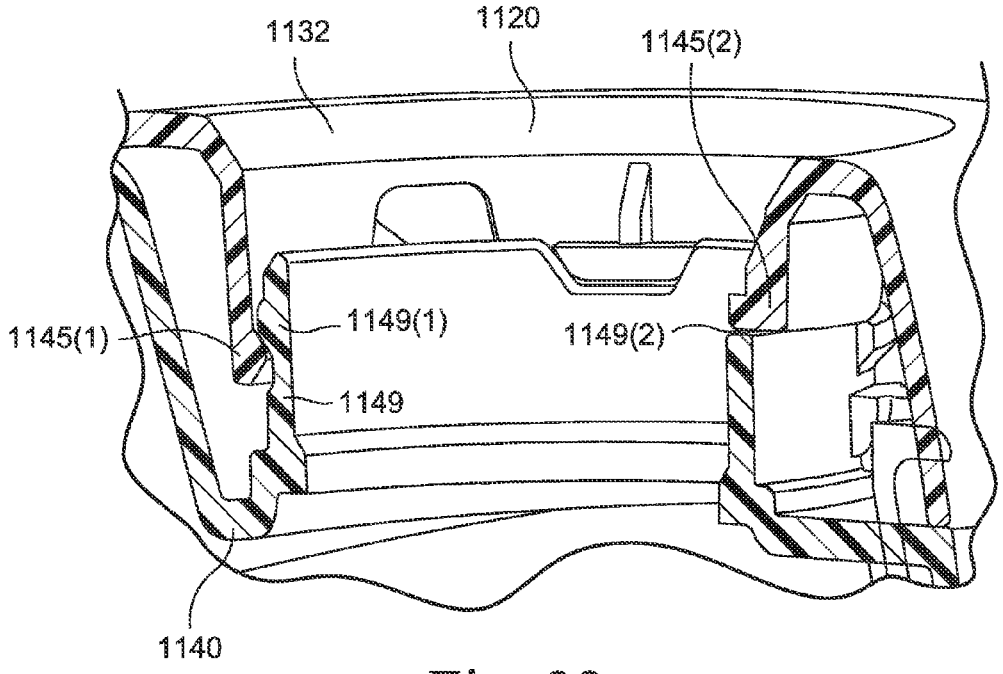
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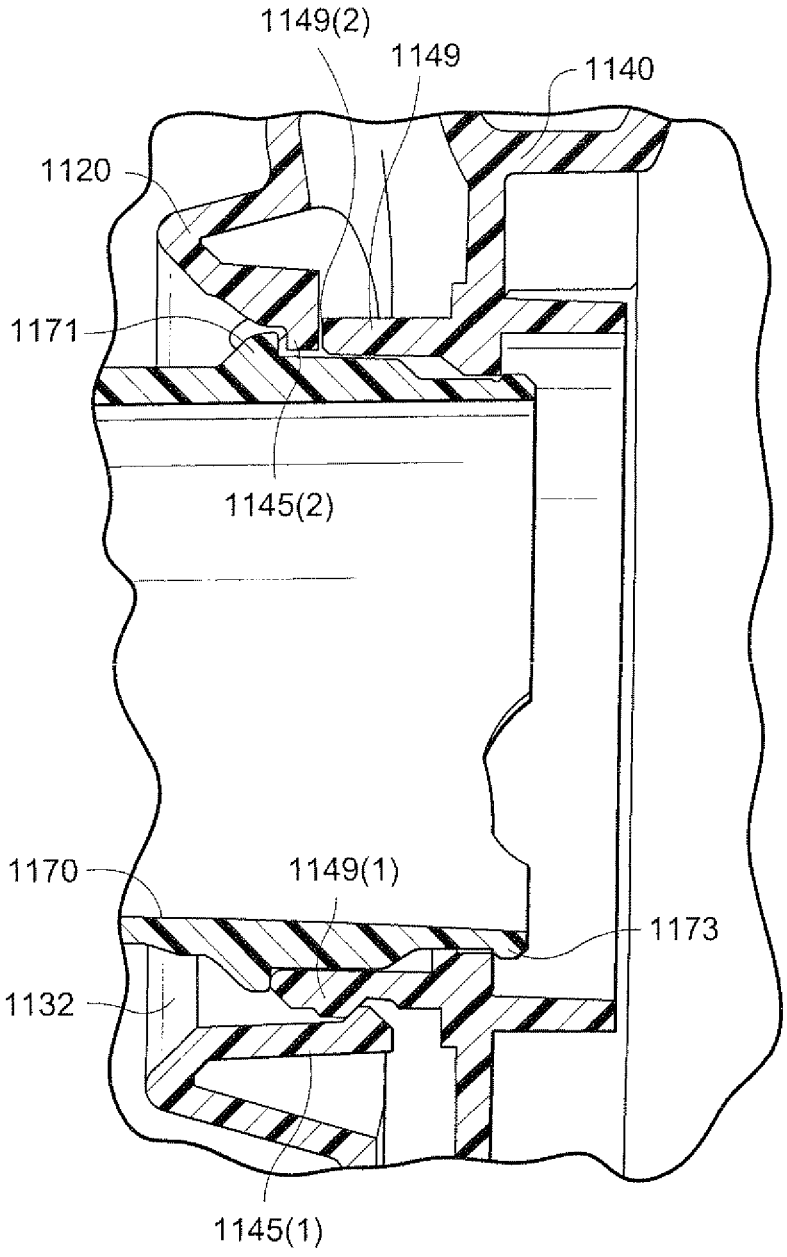
Fig. 22



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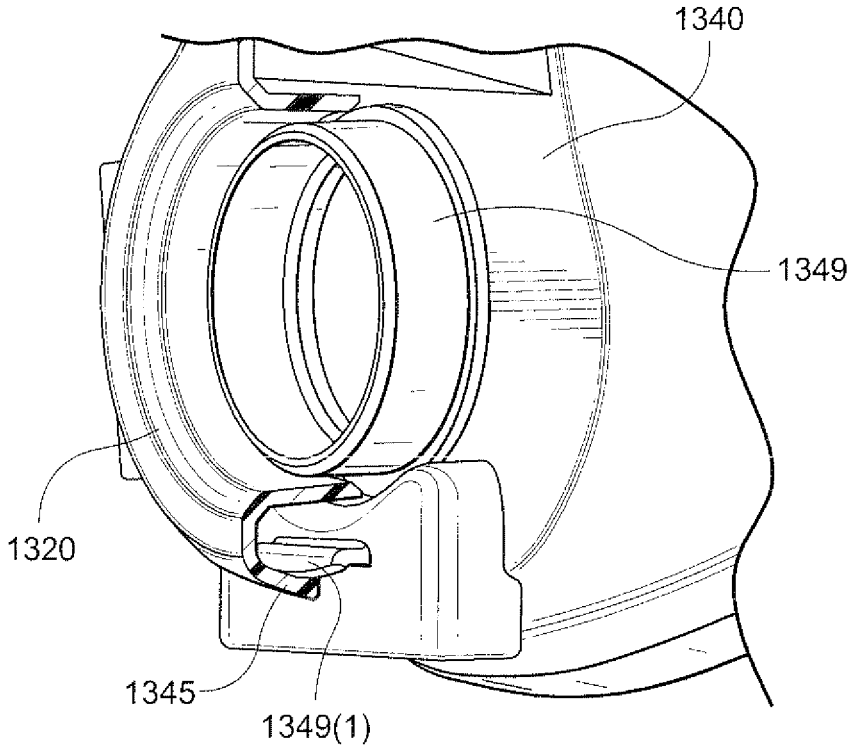

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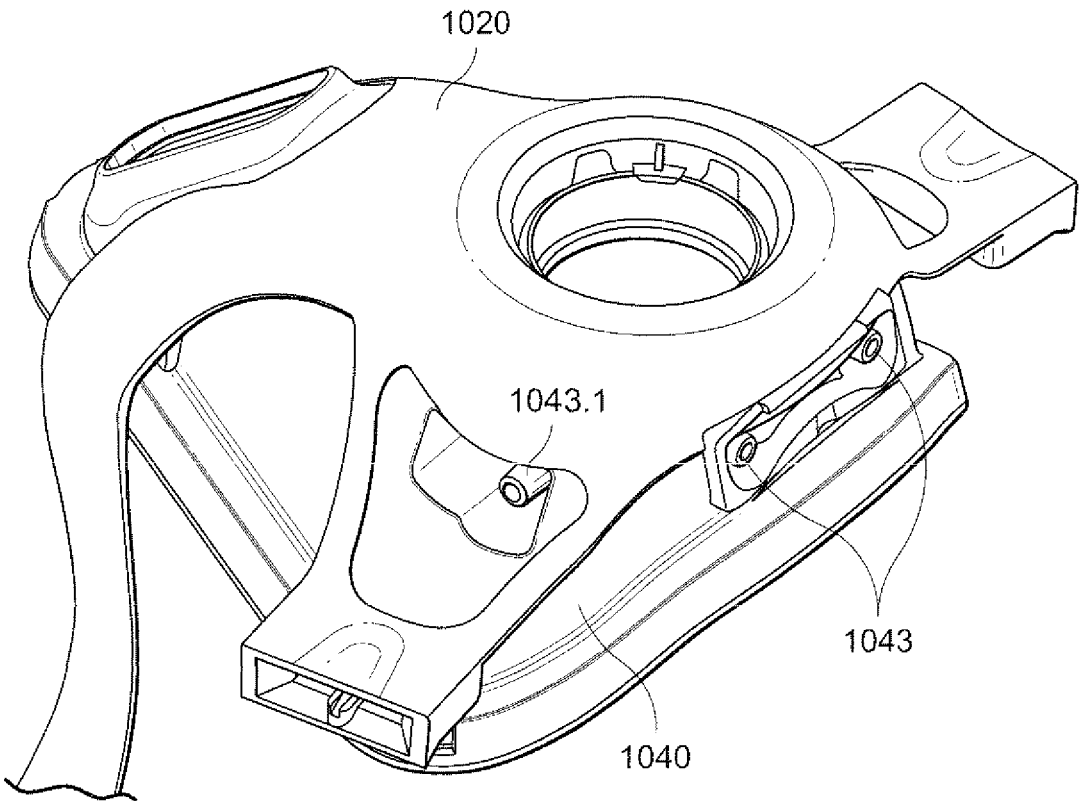

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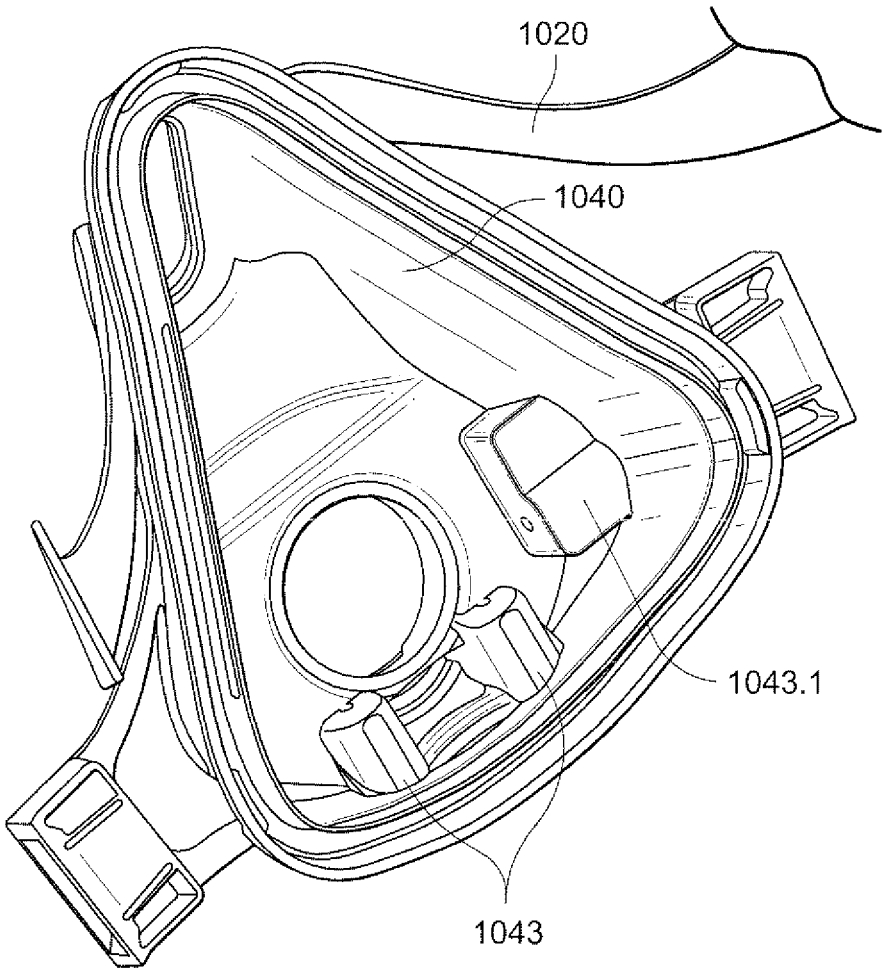

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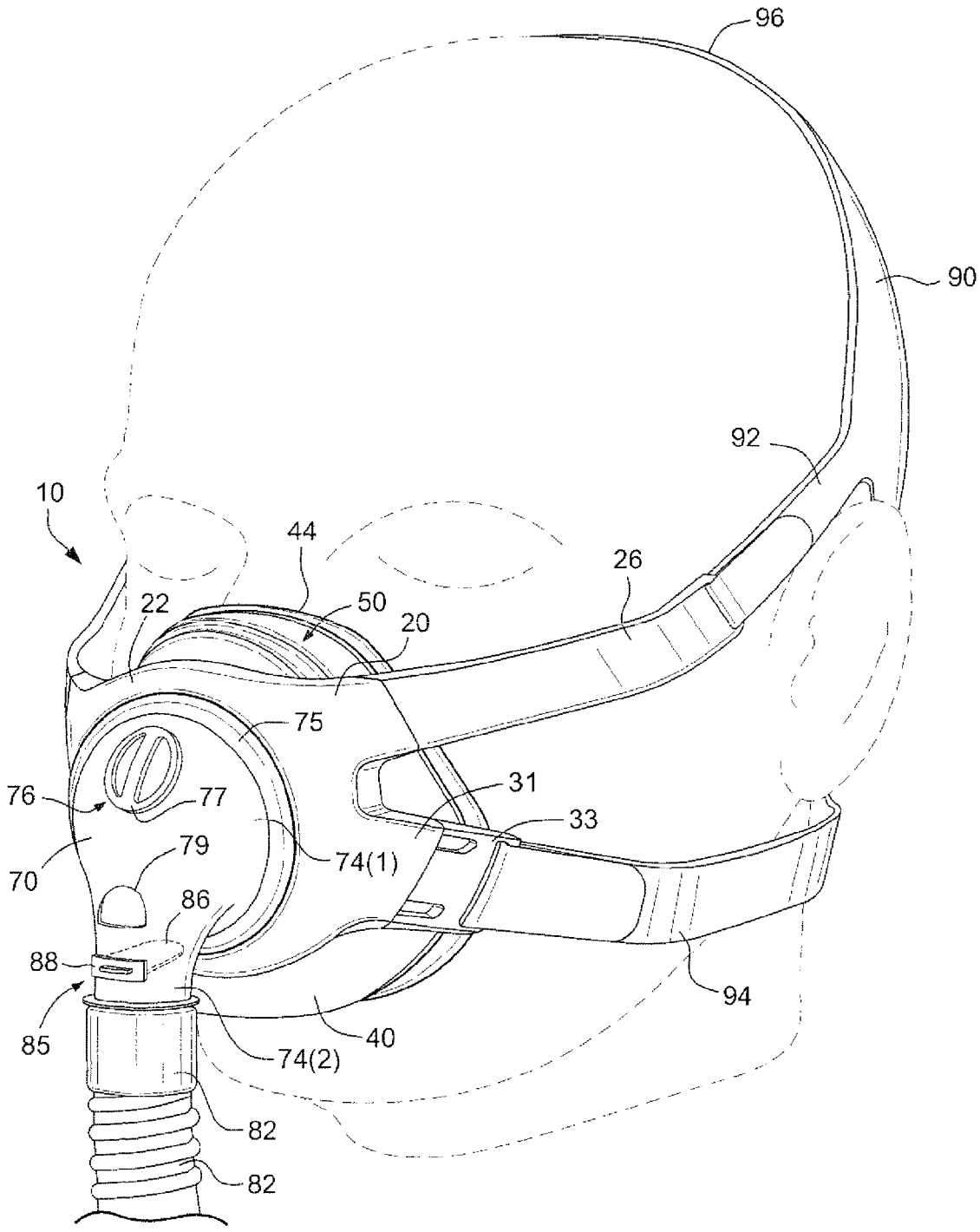
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Fig. 27

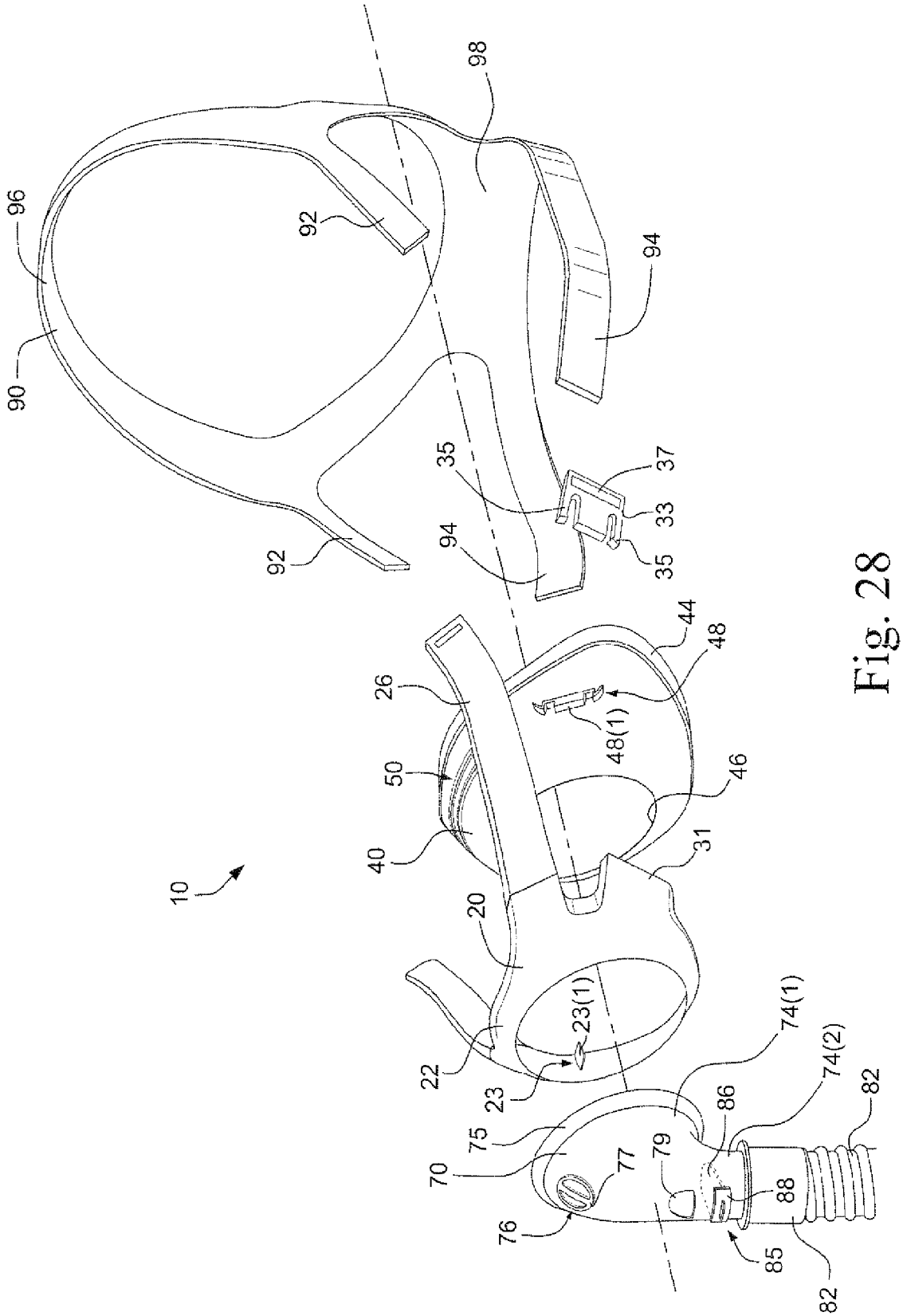
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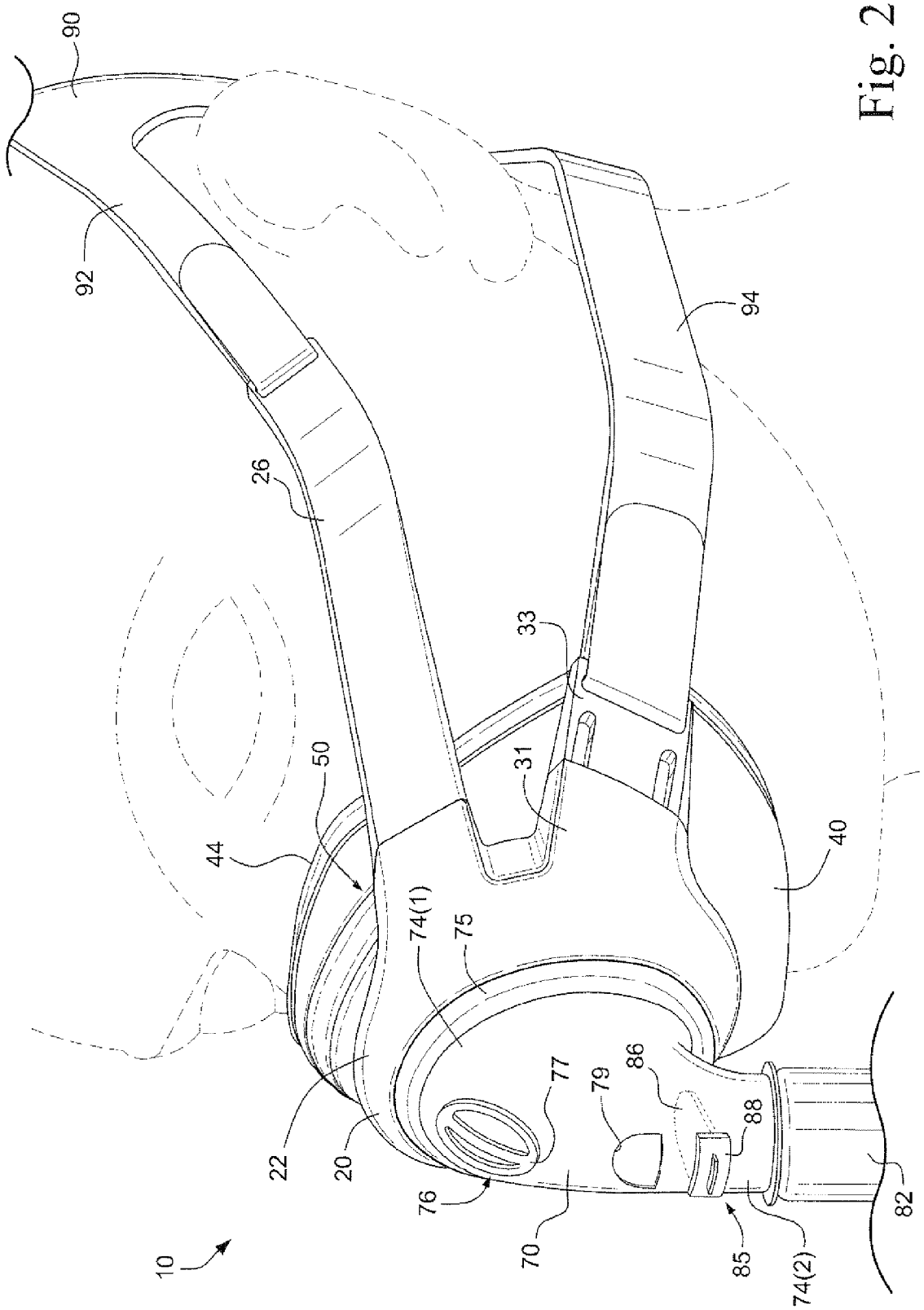
Fig. 28



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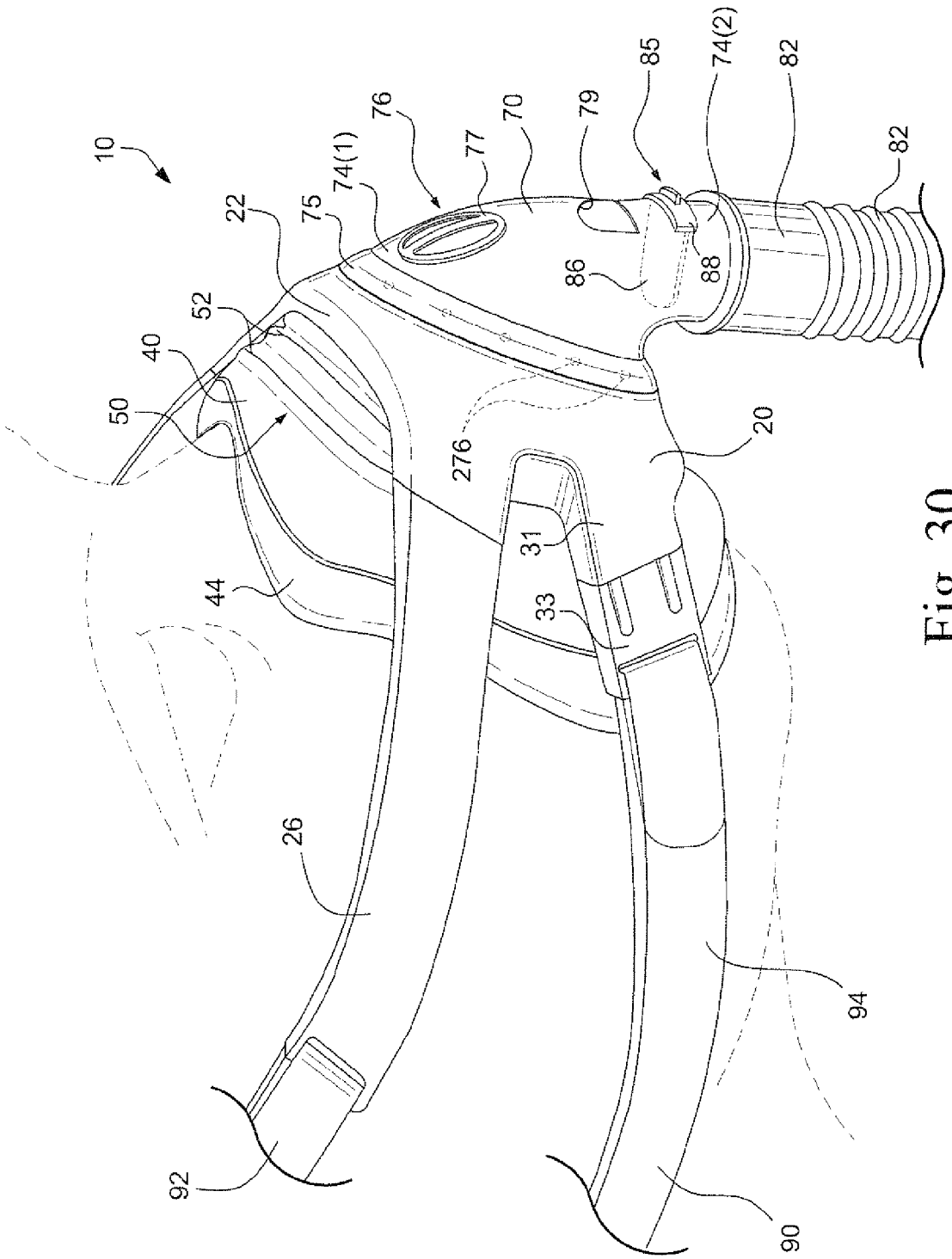
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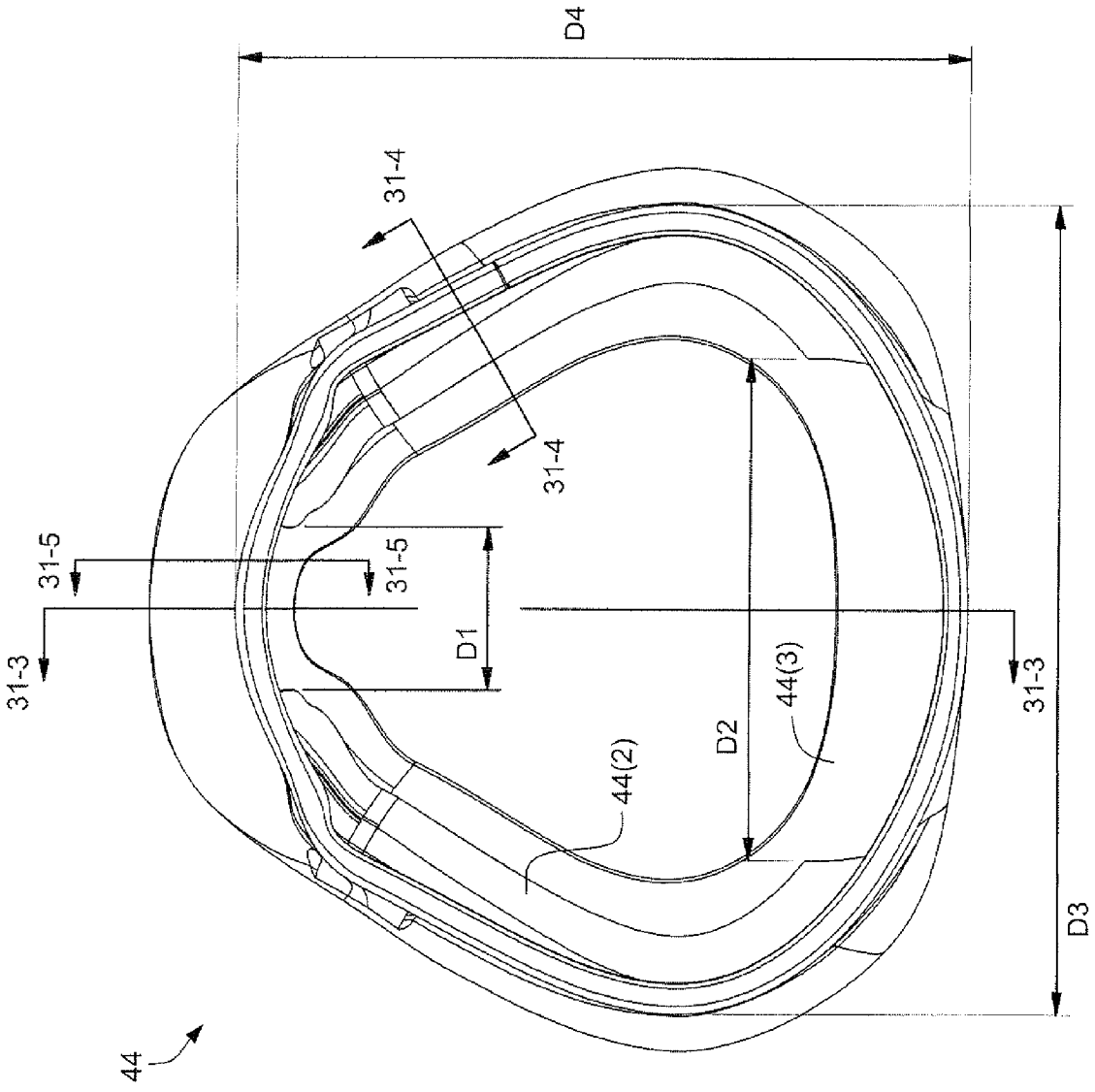
Fig. 30



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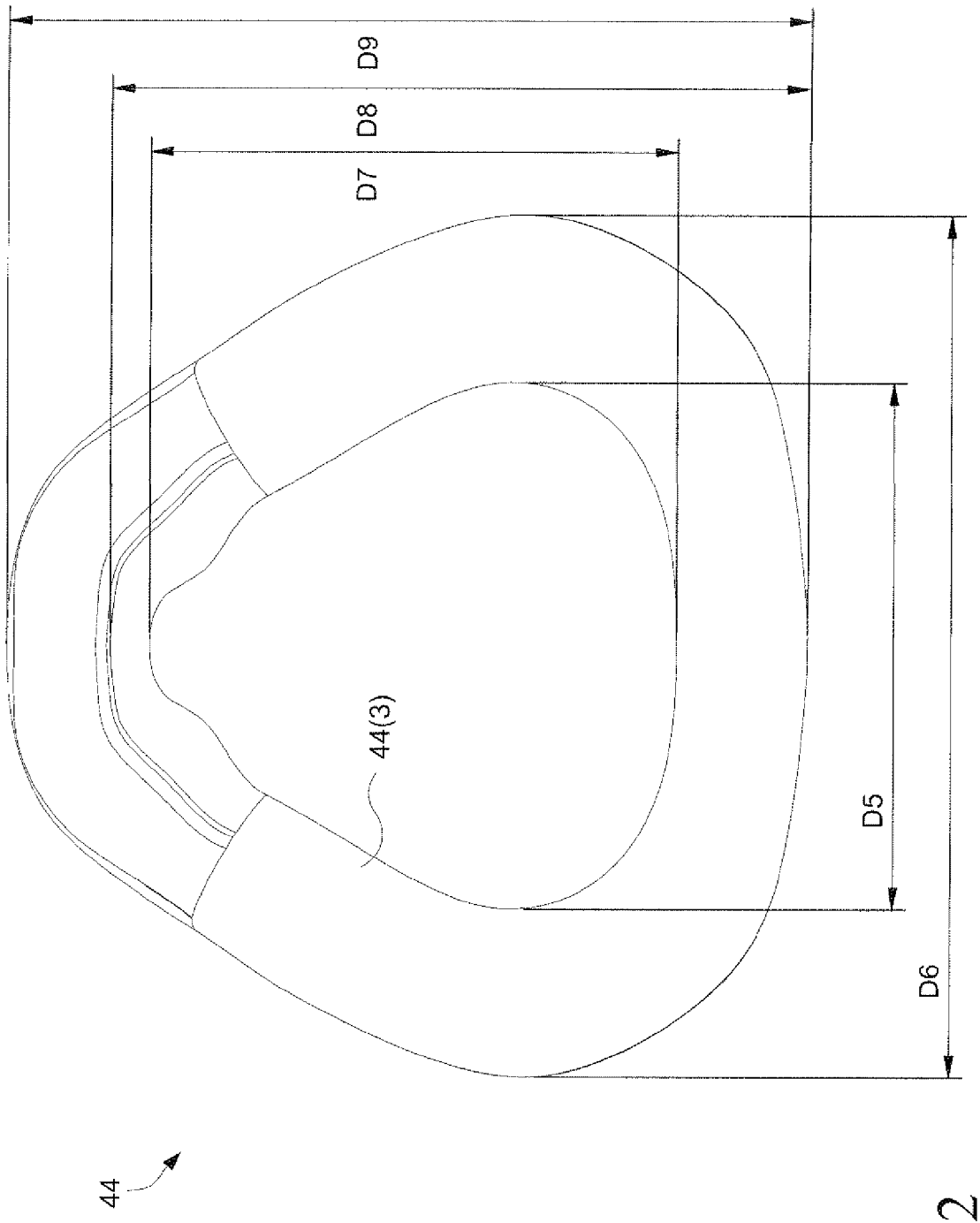
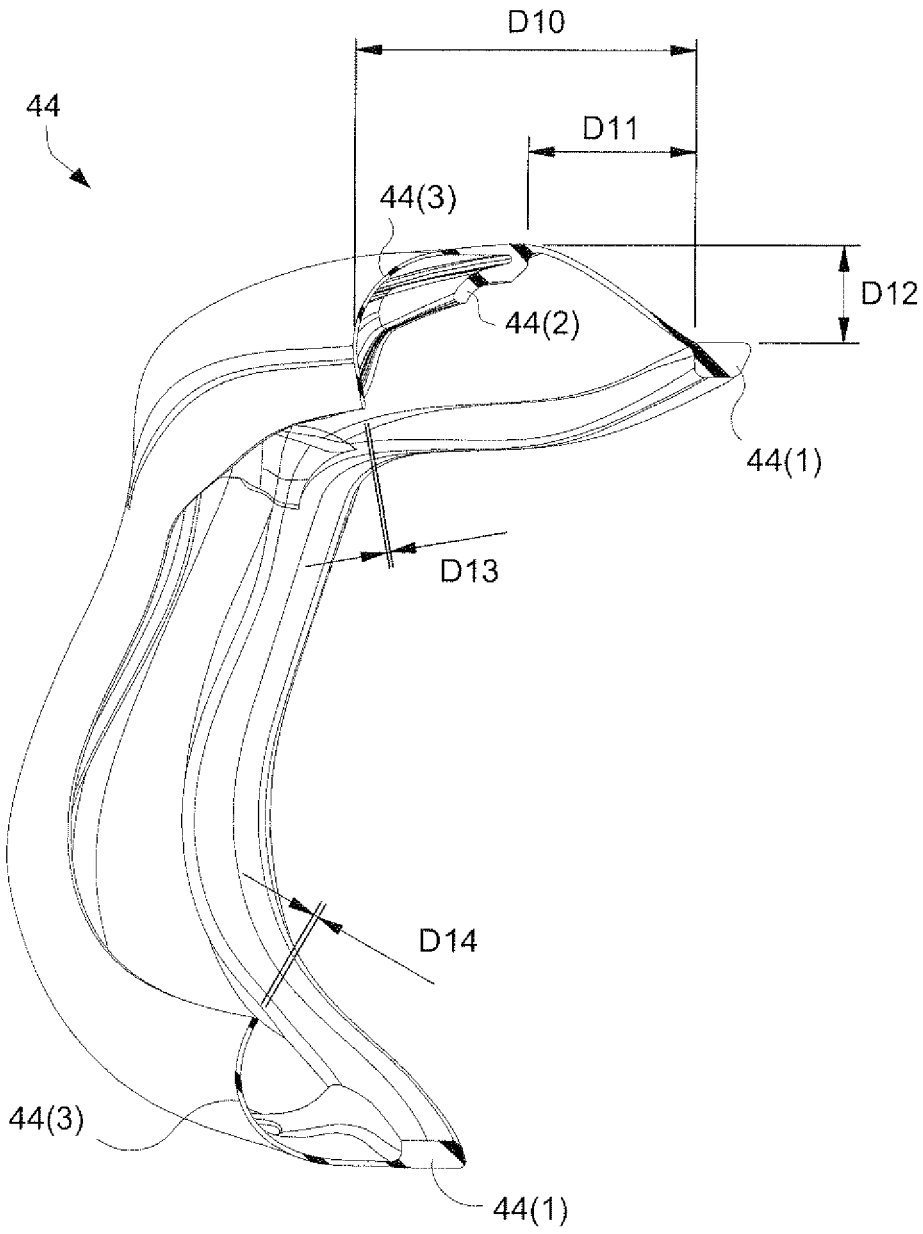


Fig. 31-2



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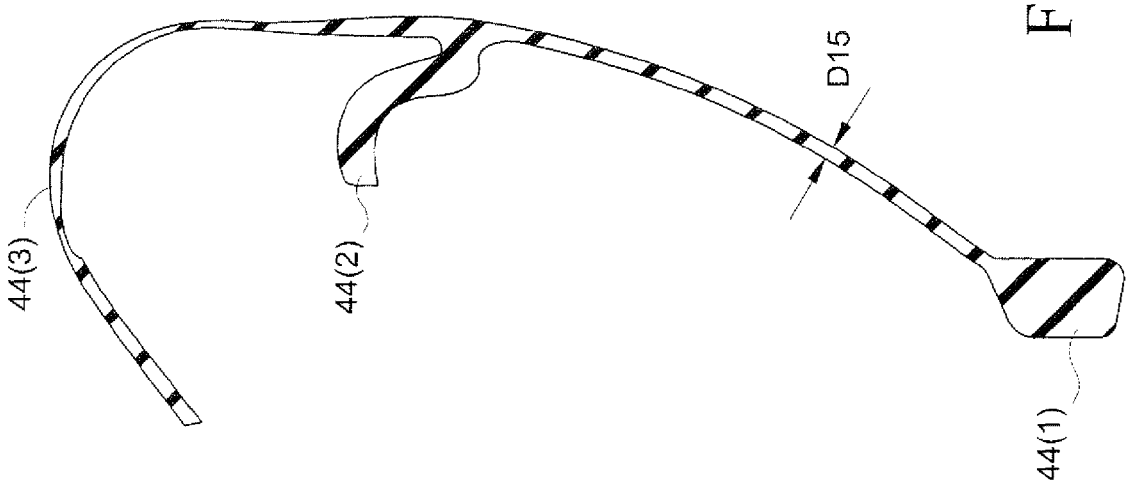

Fig. 31-5

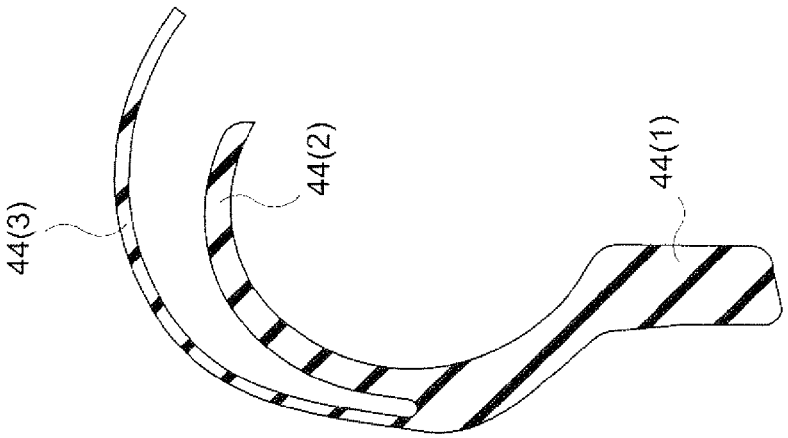

Fig. 31-4

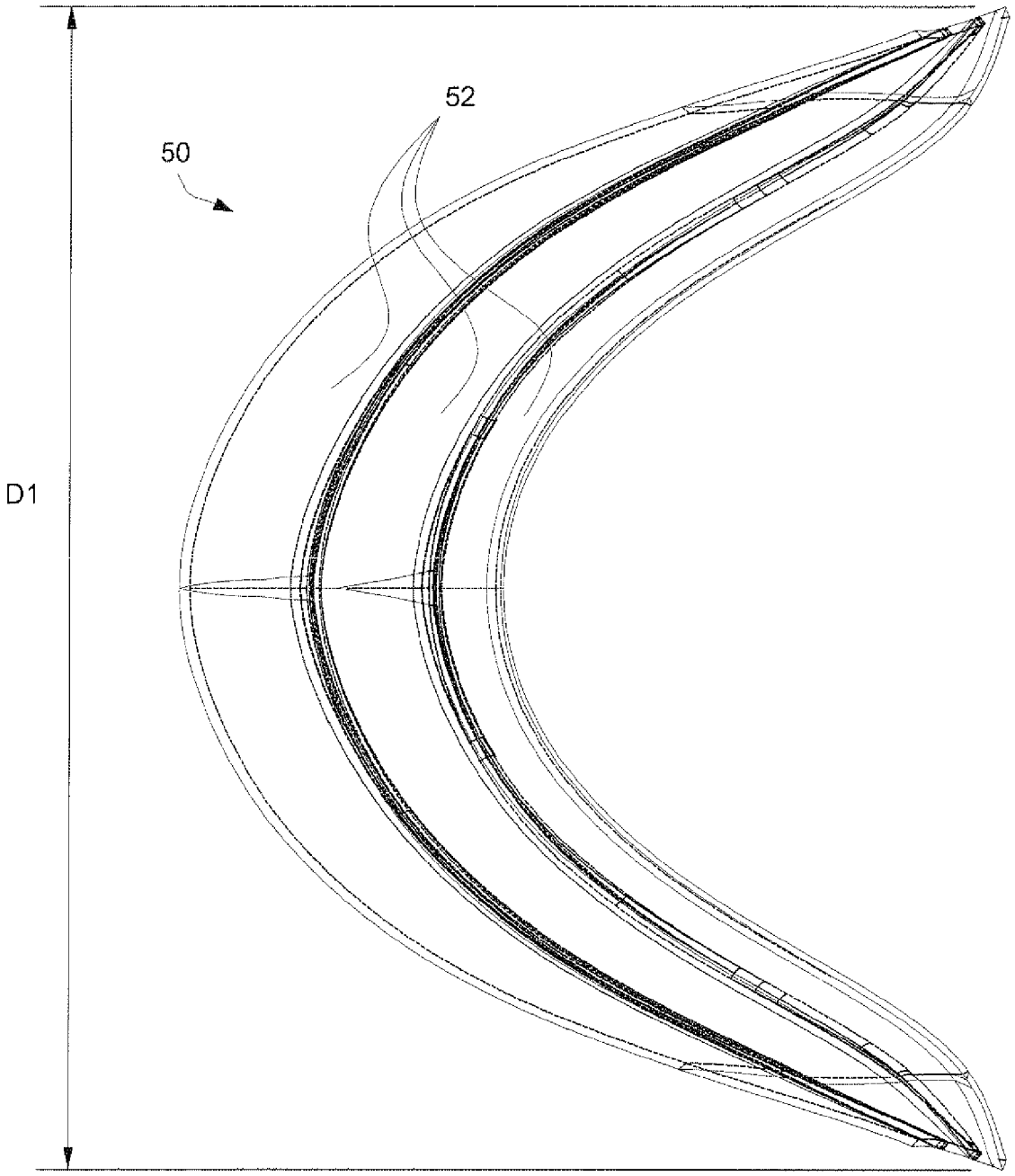

Fig. 32-1

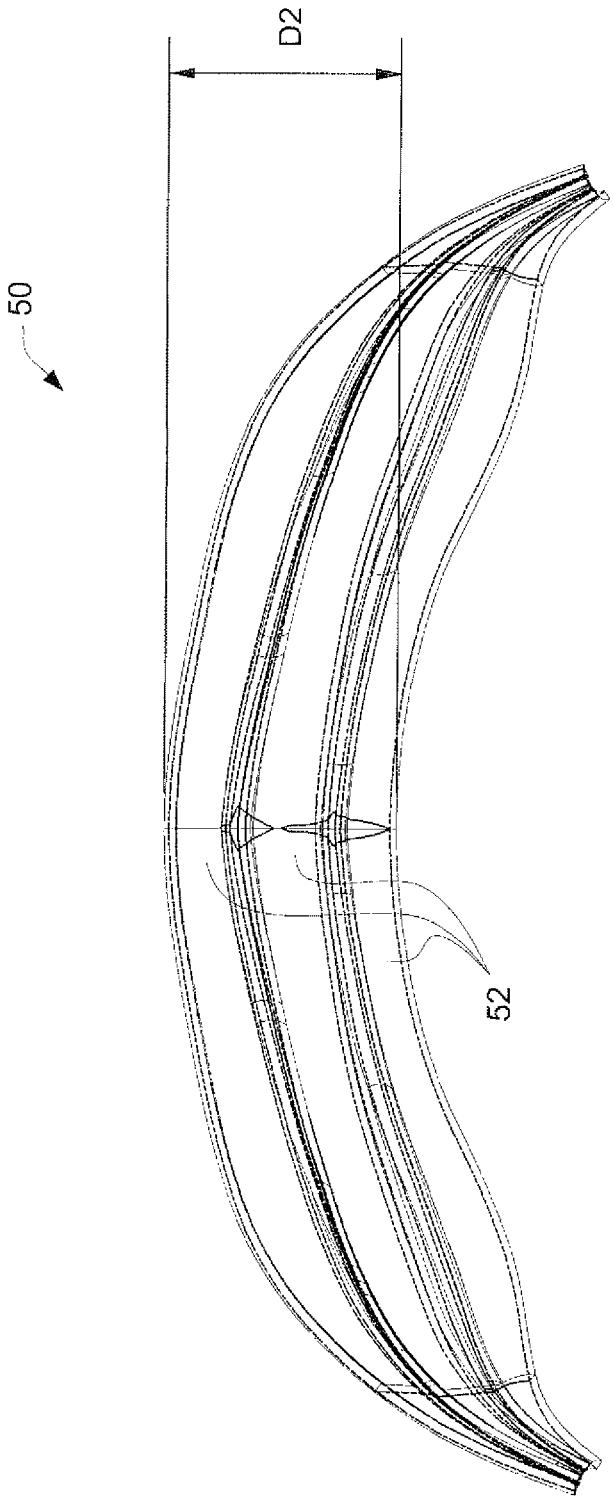

Fig. 32-2

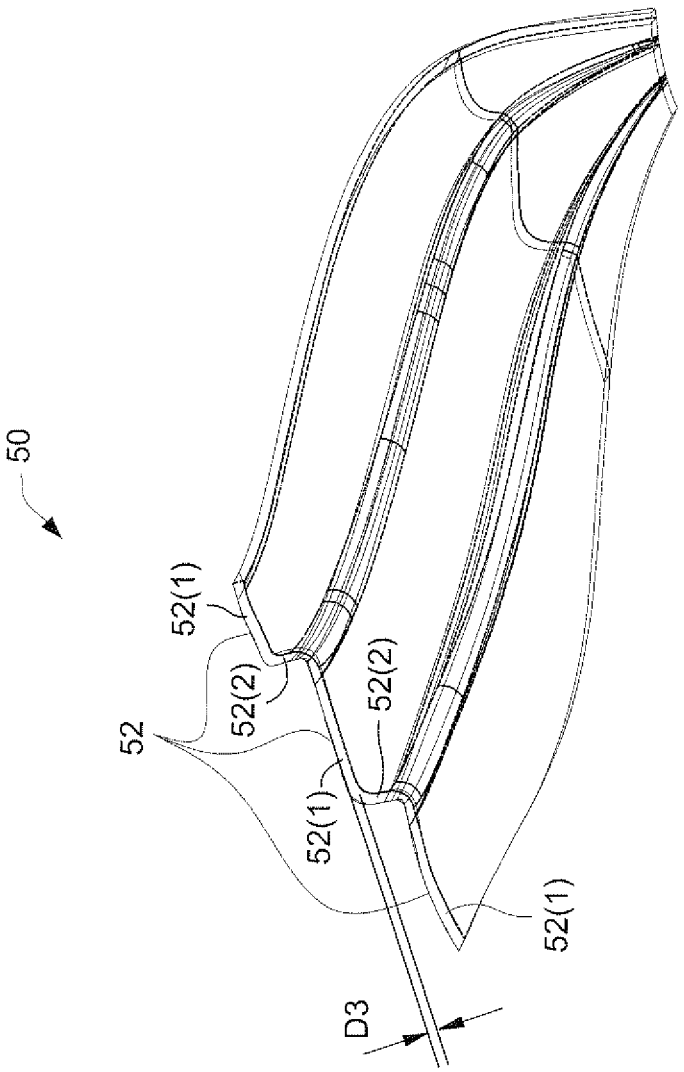

Fig. 32-3

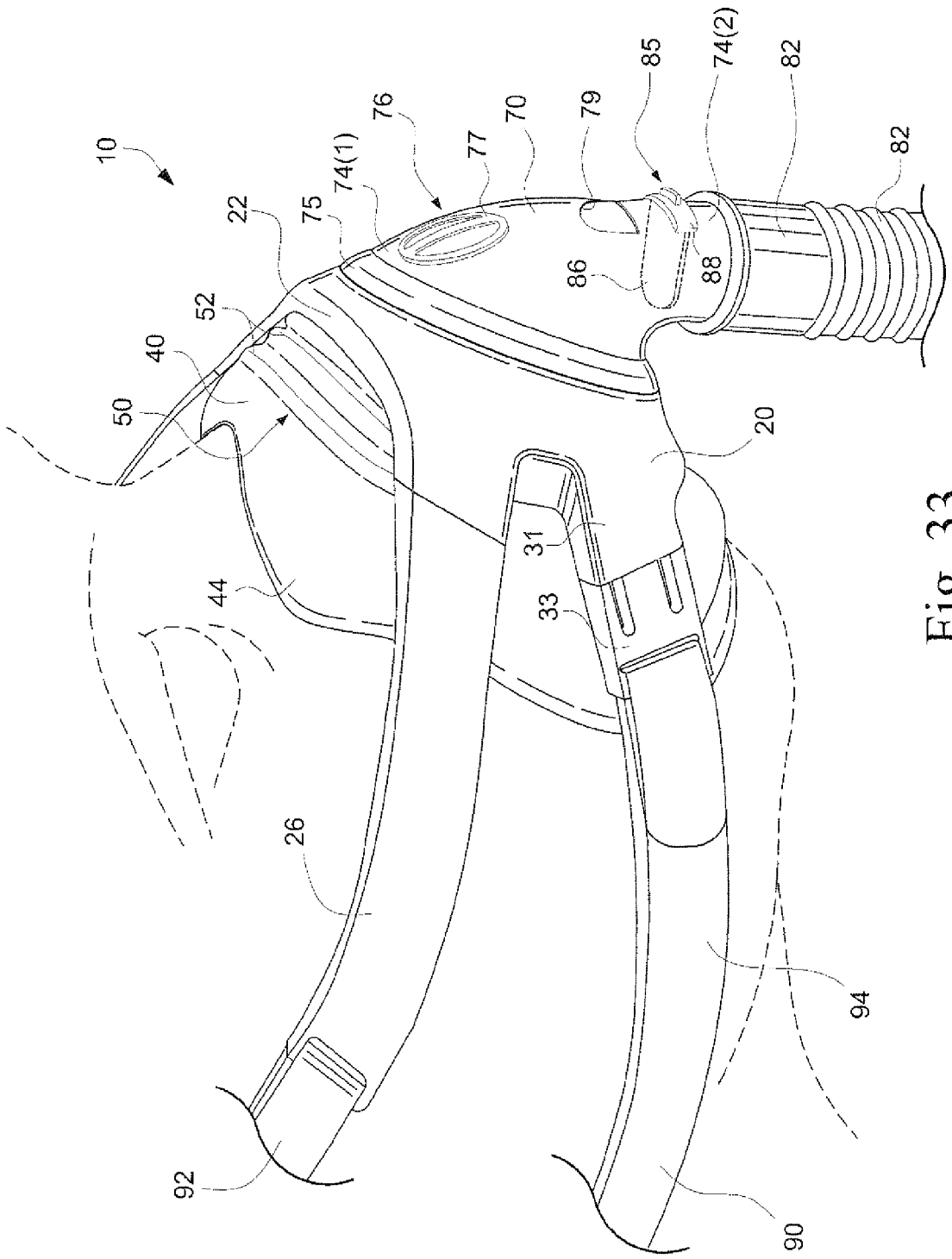
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Fig. 33

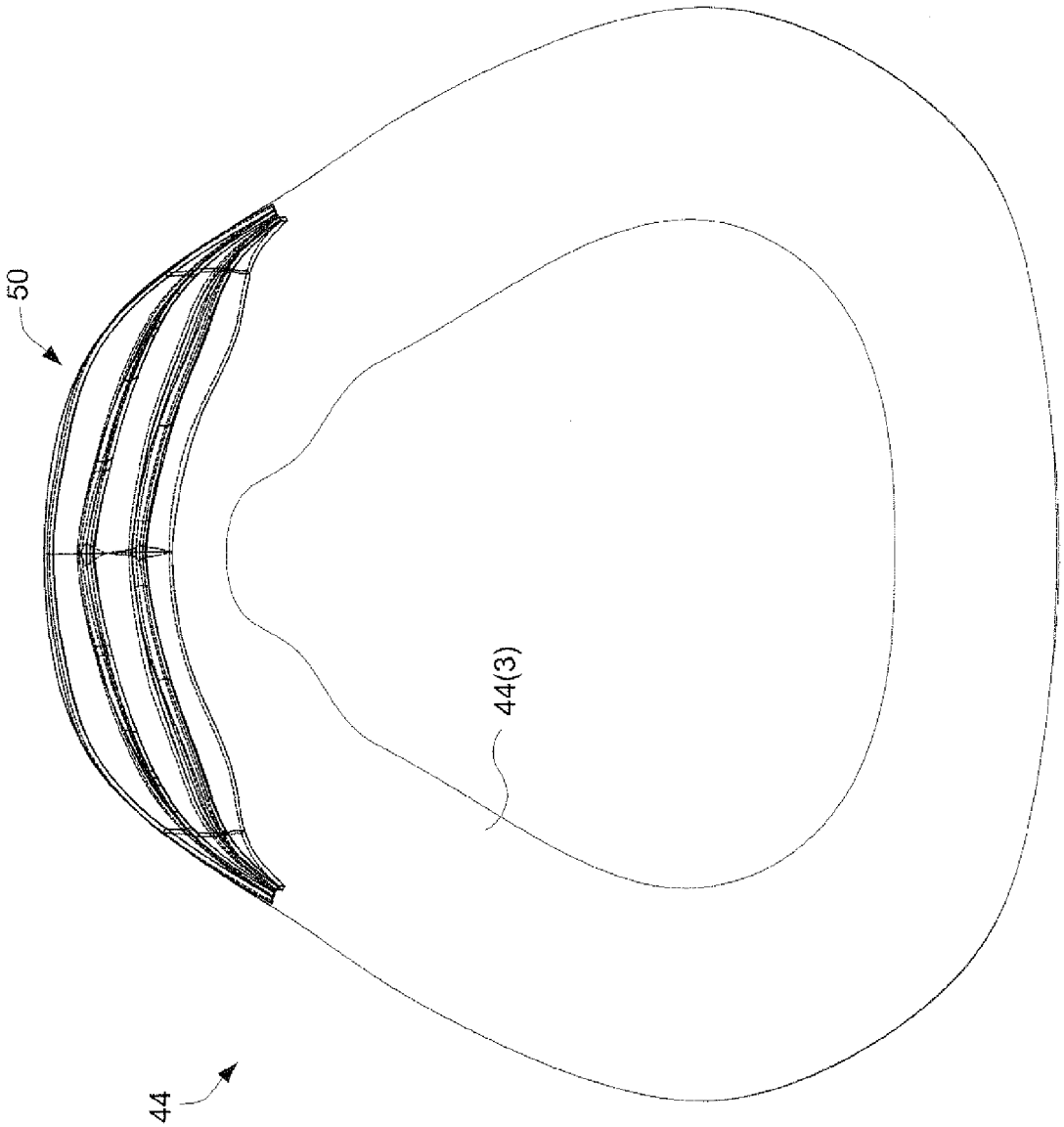

Fig. 34

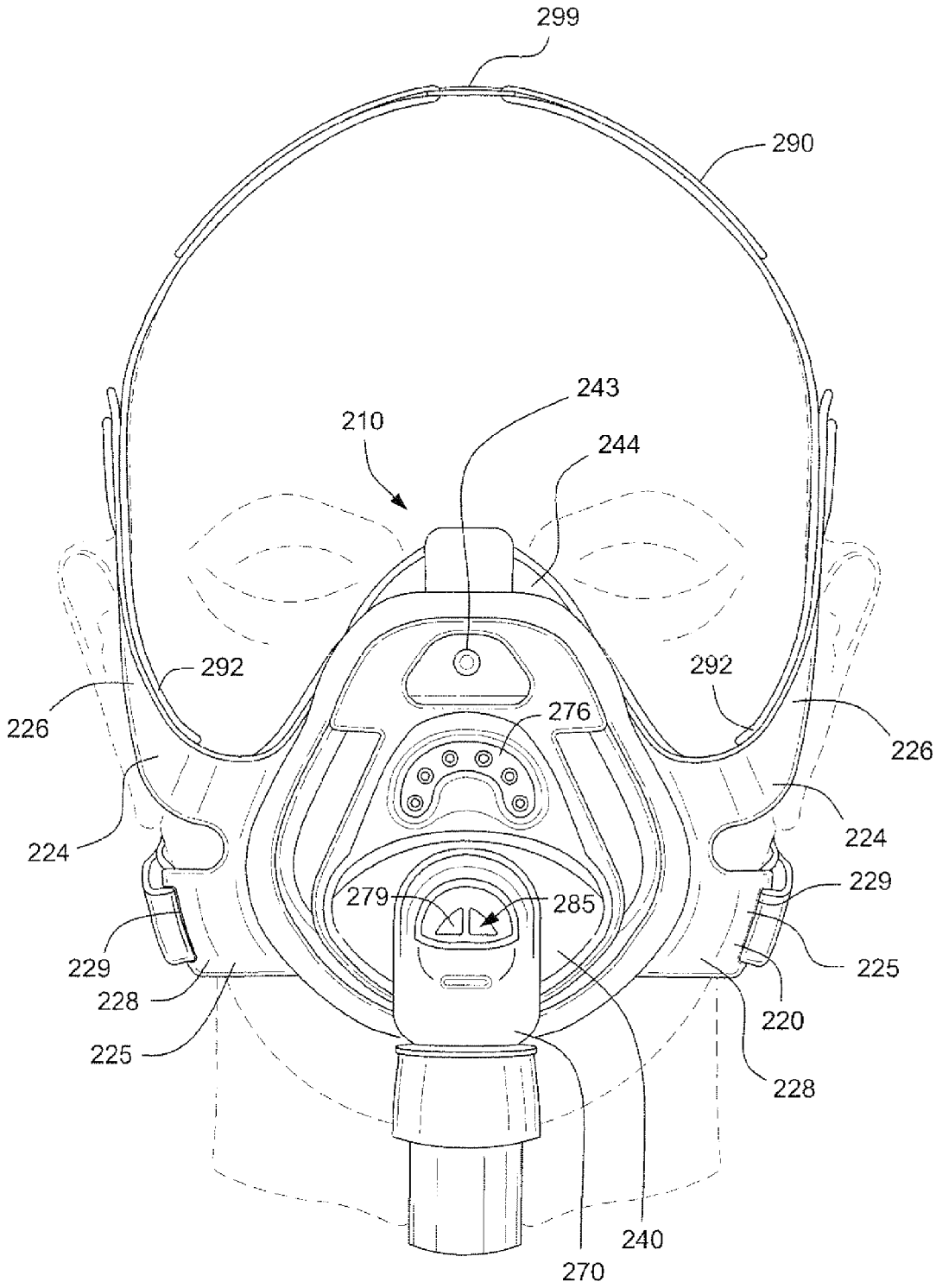
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Fig. 35-1

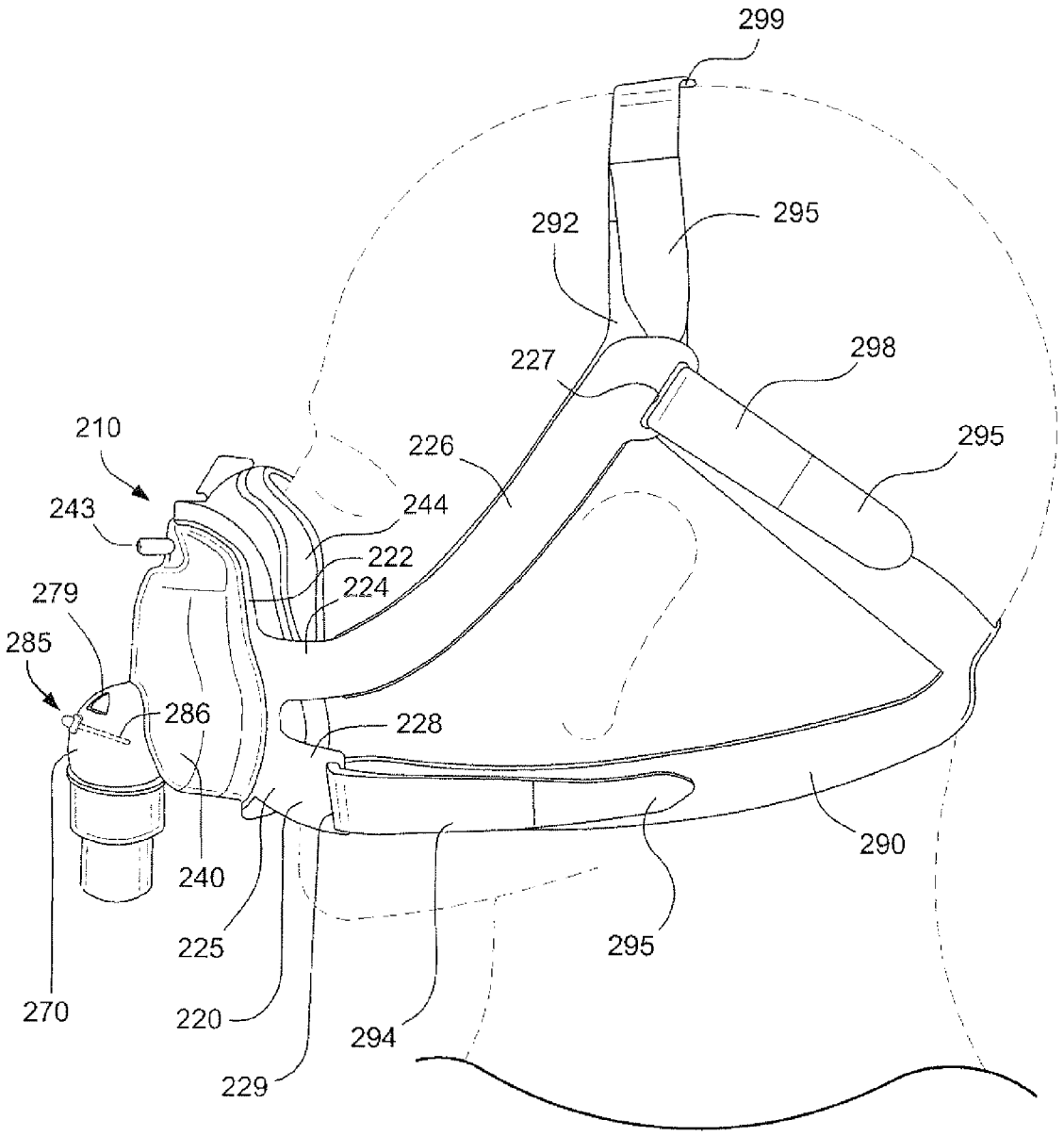
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Fig. 35-2

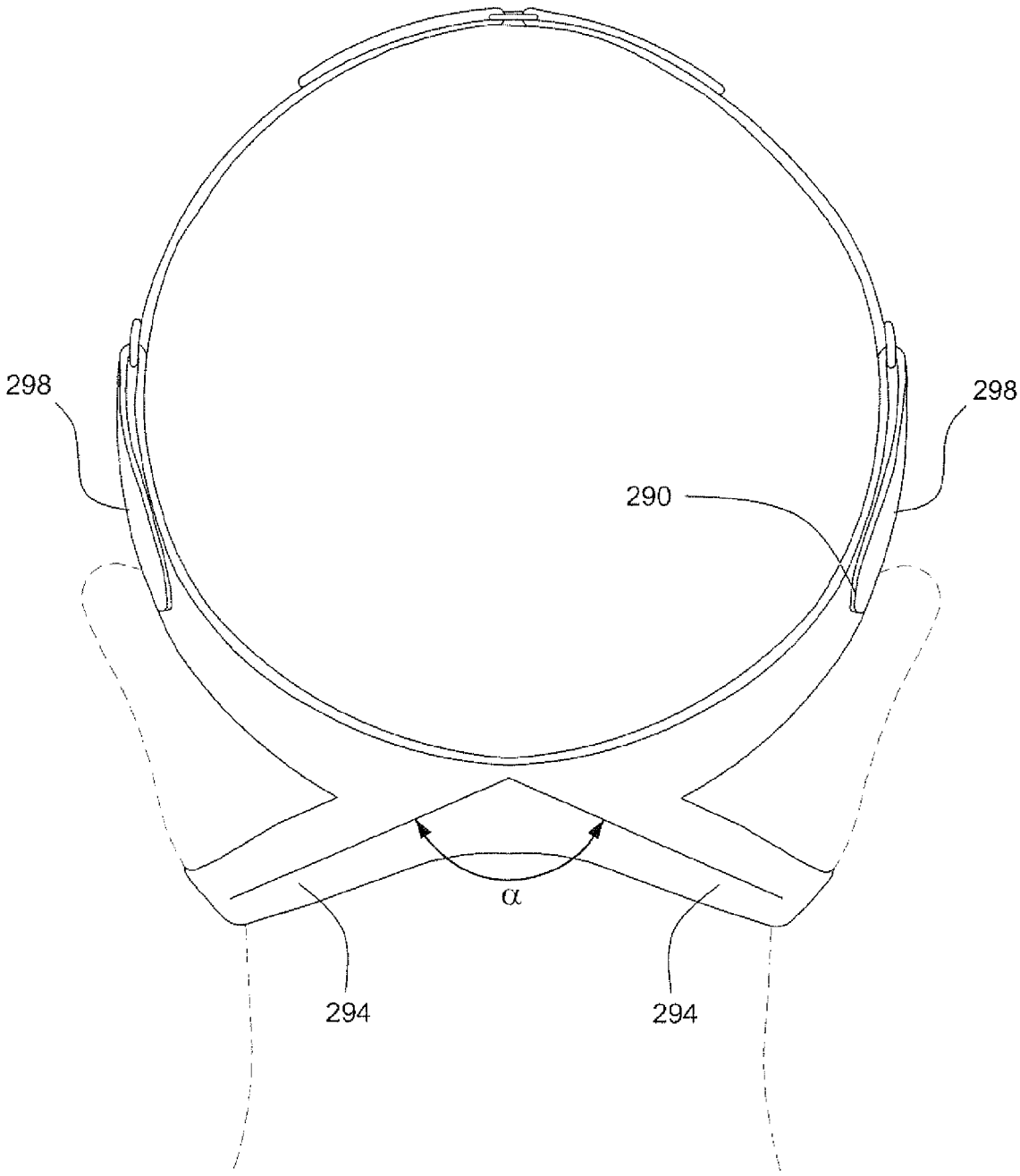

Fig. 35-3

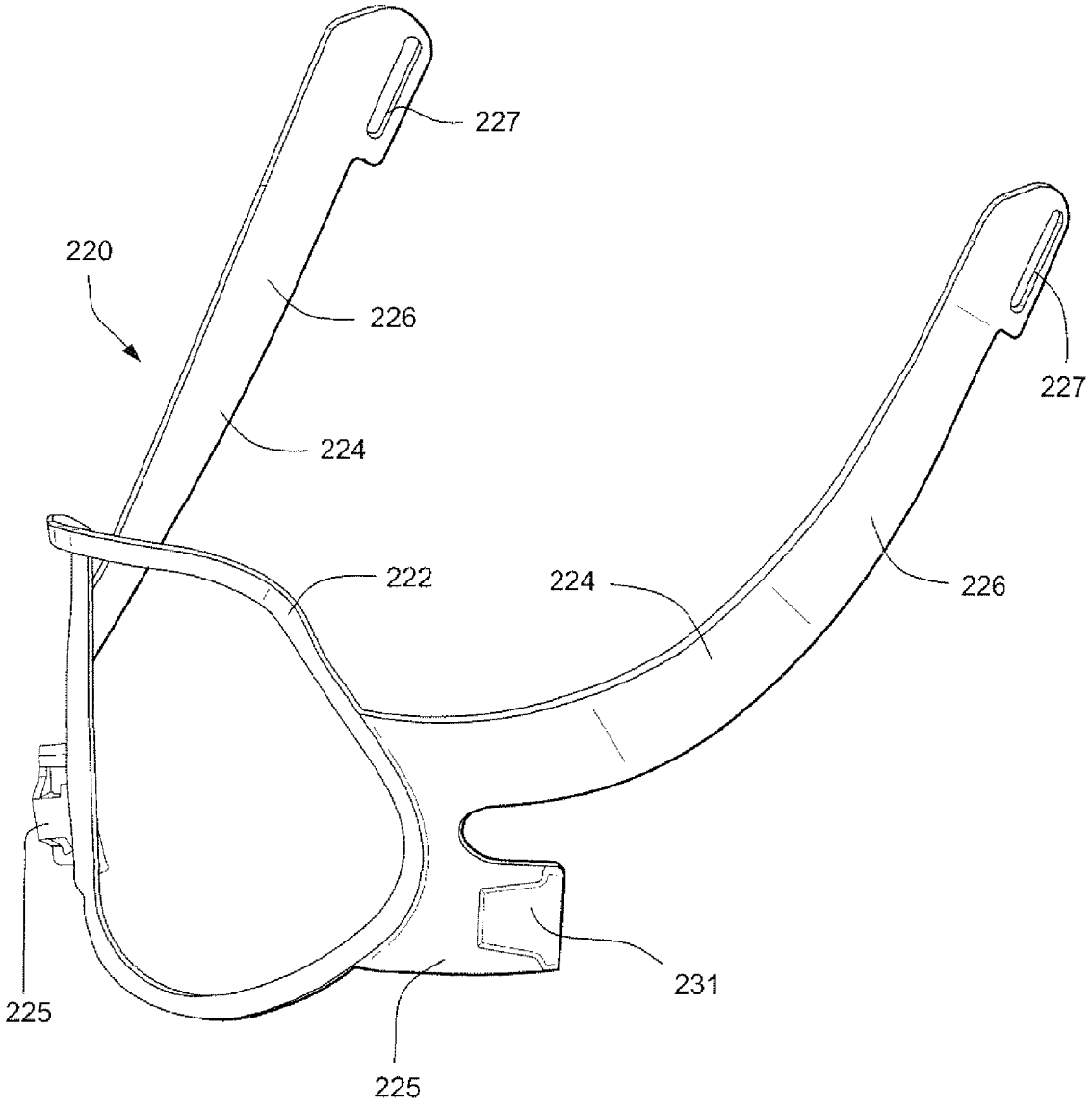

Fig. 36

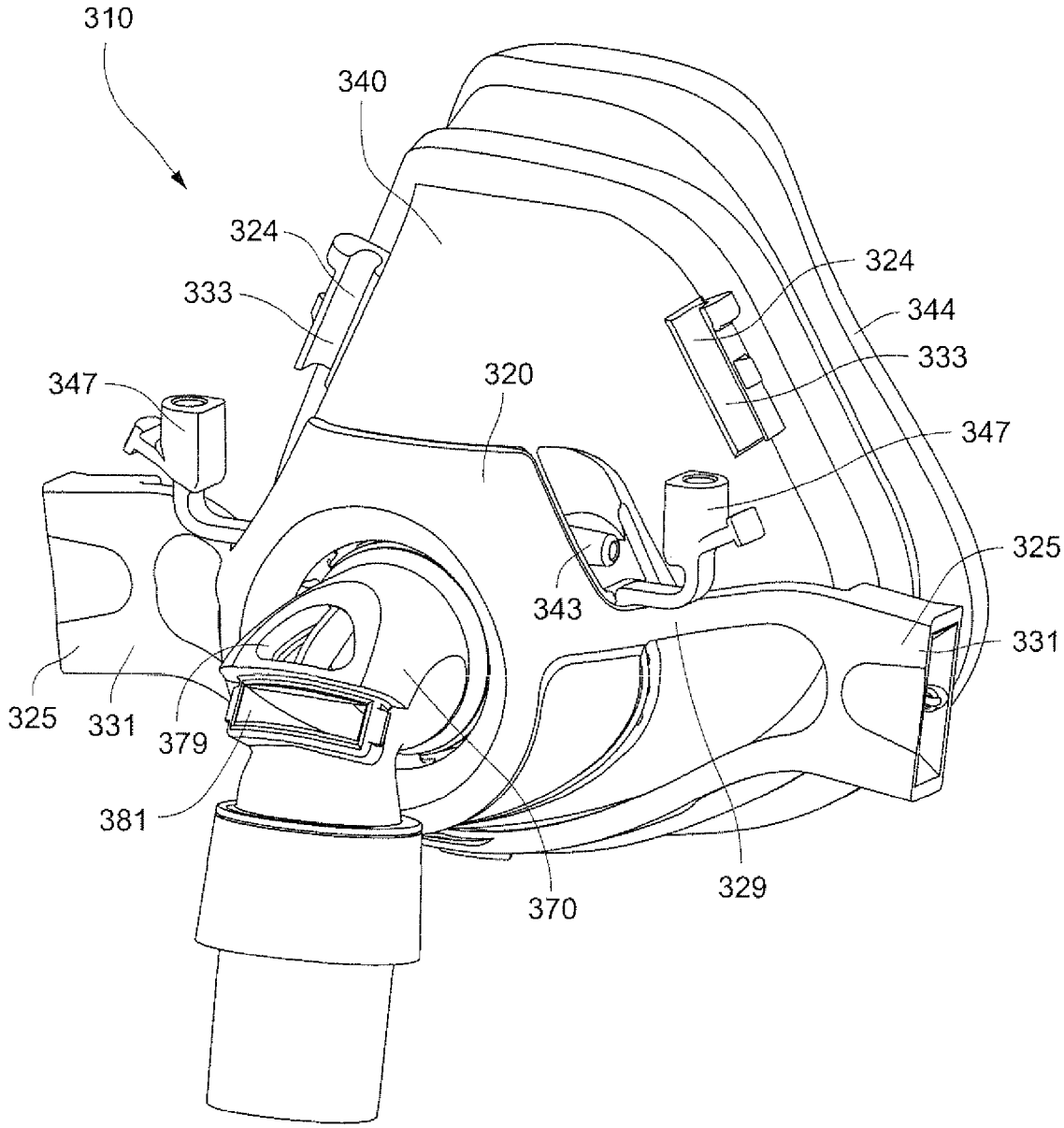
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Fig. 37-1

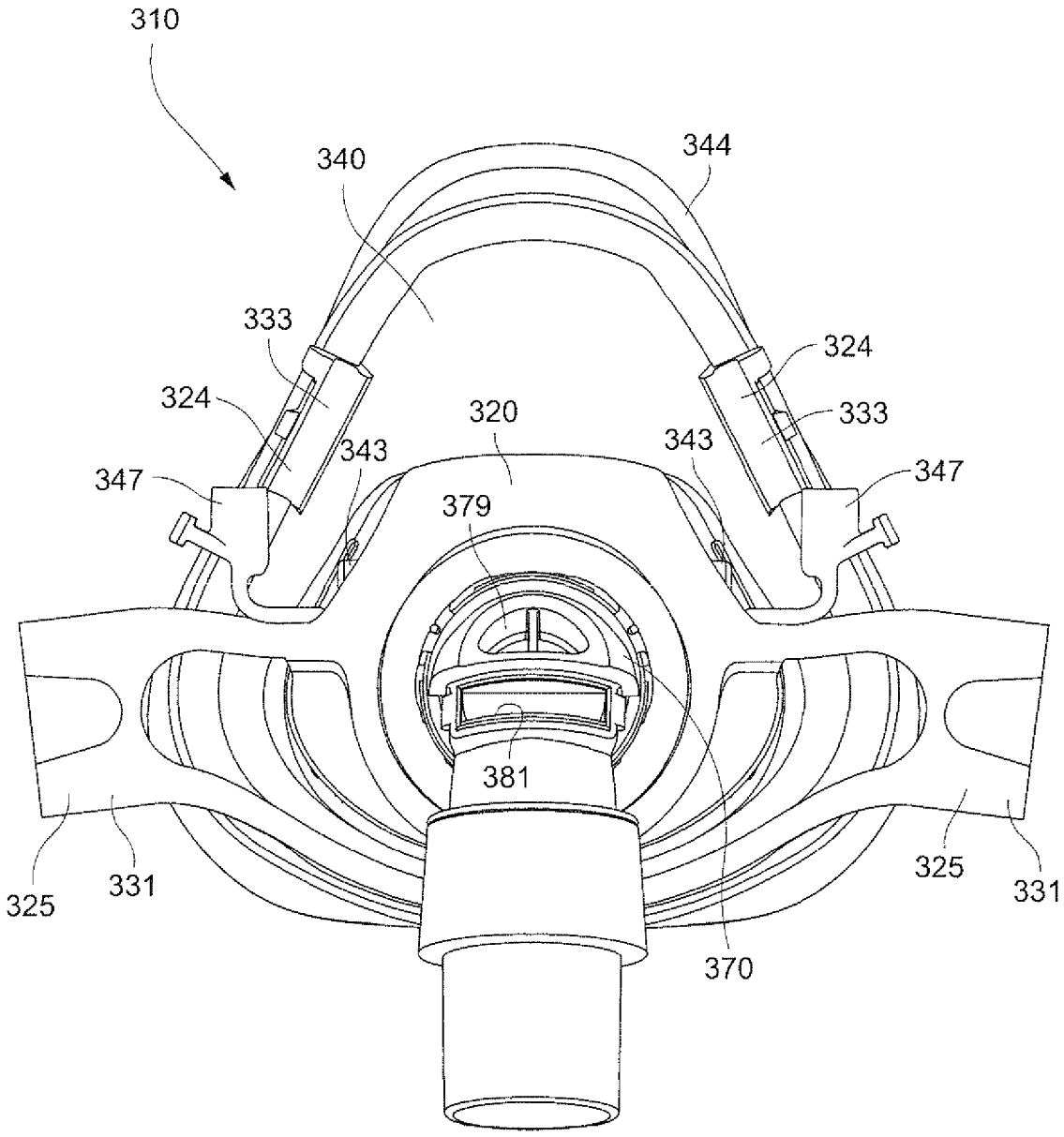
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Fig. 37-2

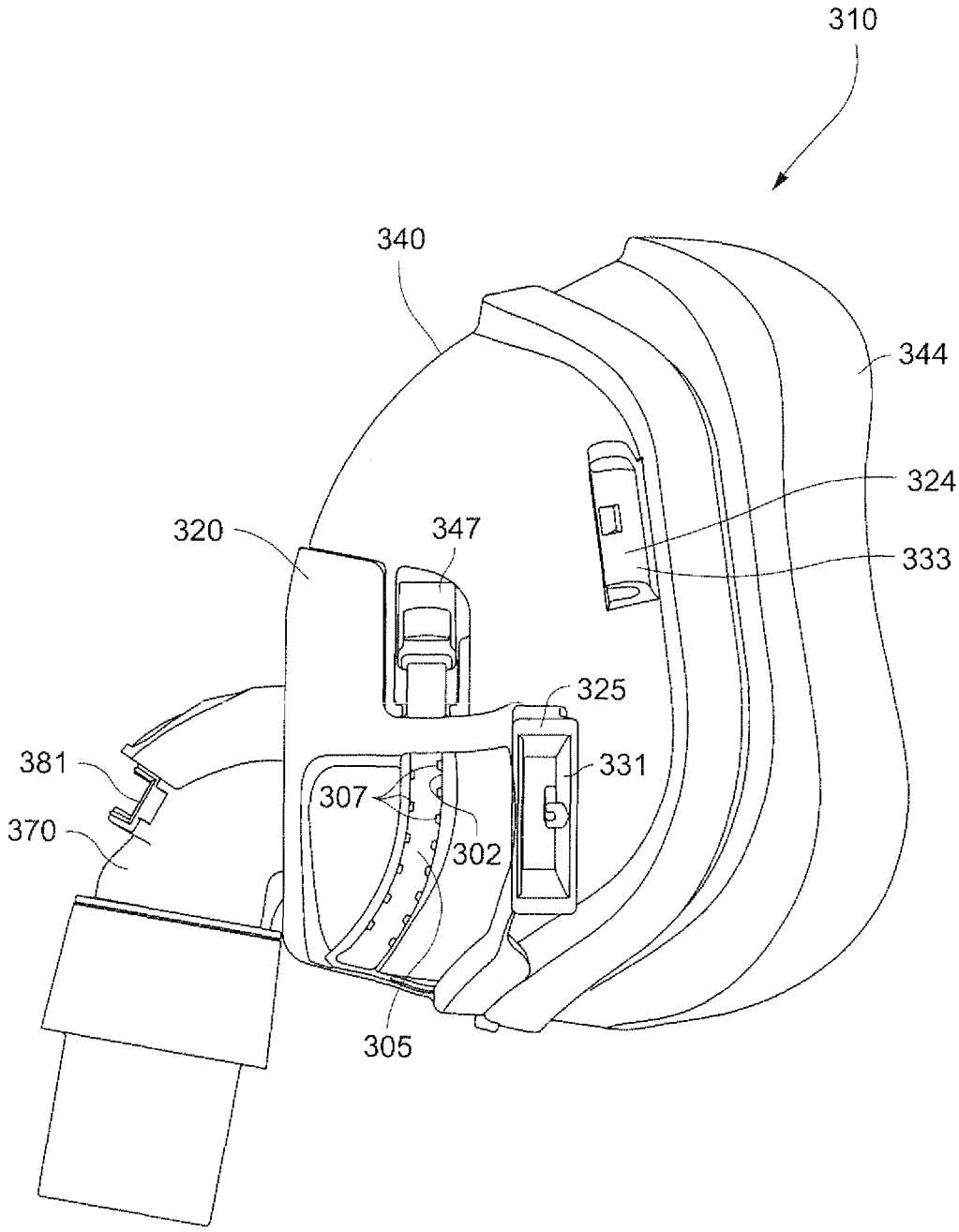

Fig. 37-3

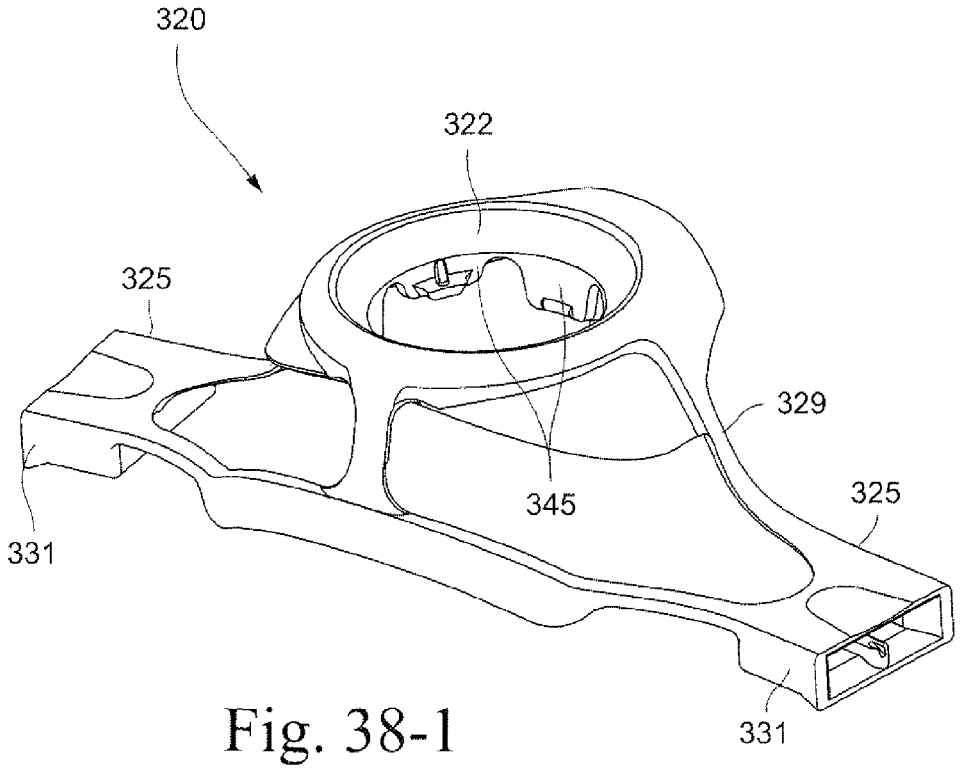

Fig. 38-1

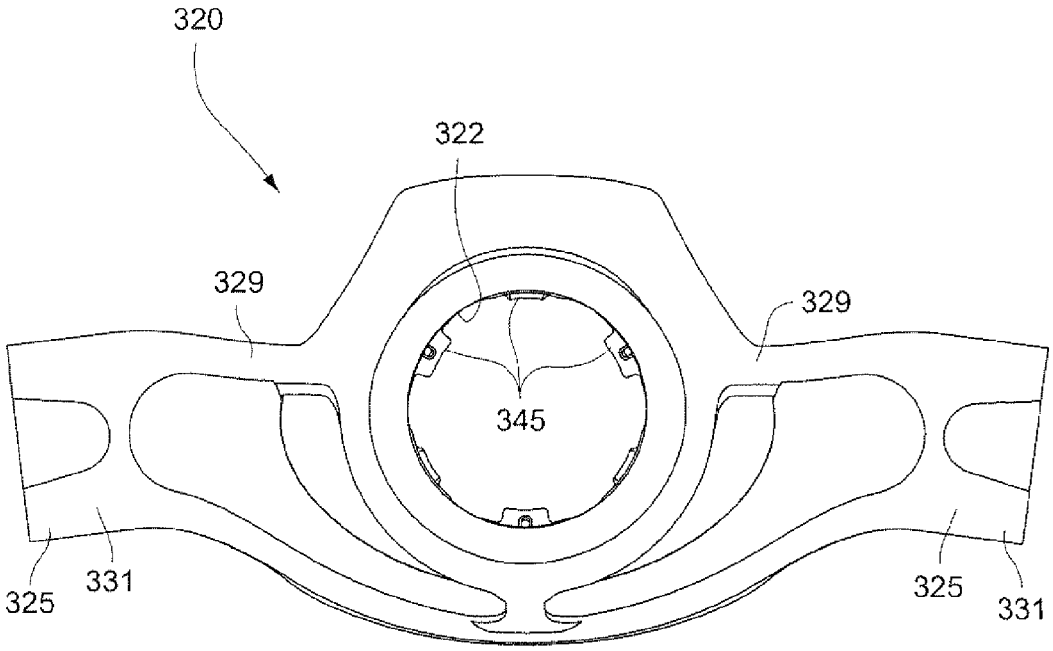

Fig. 38-2

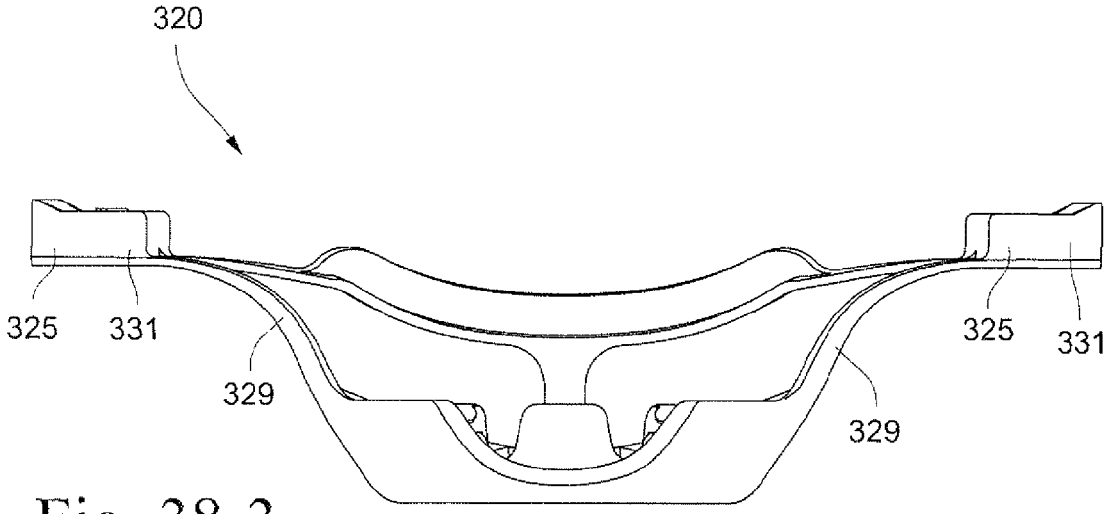

Fig. 38-3

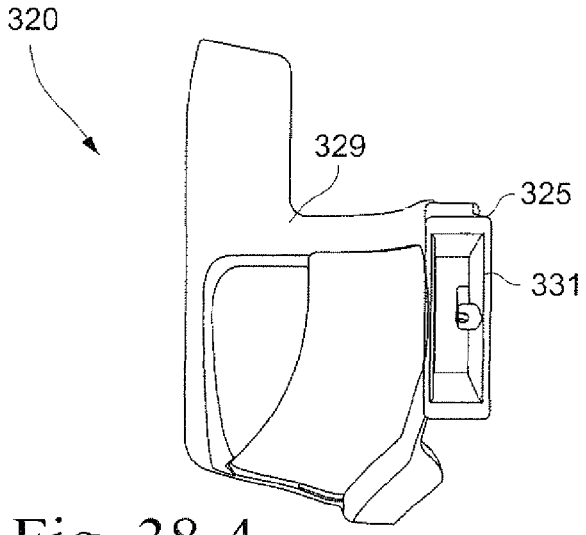

Fig. 38-4

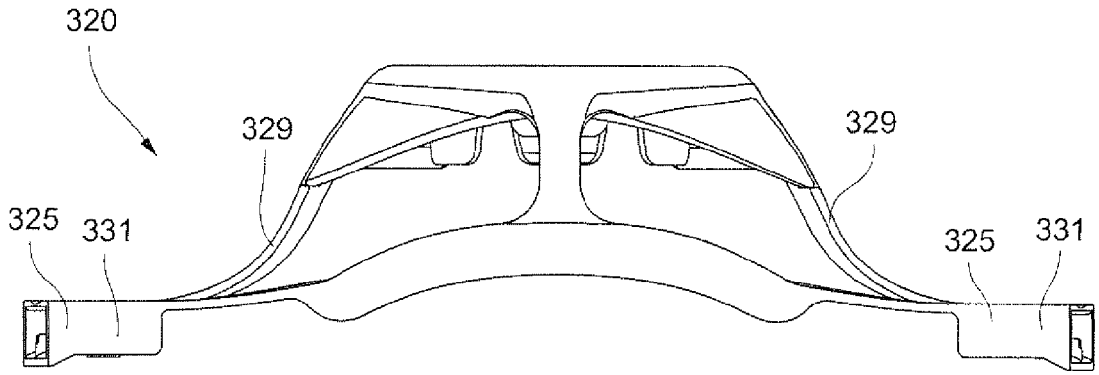

Fig. 38-5

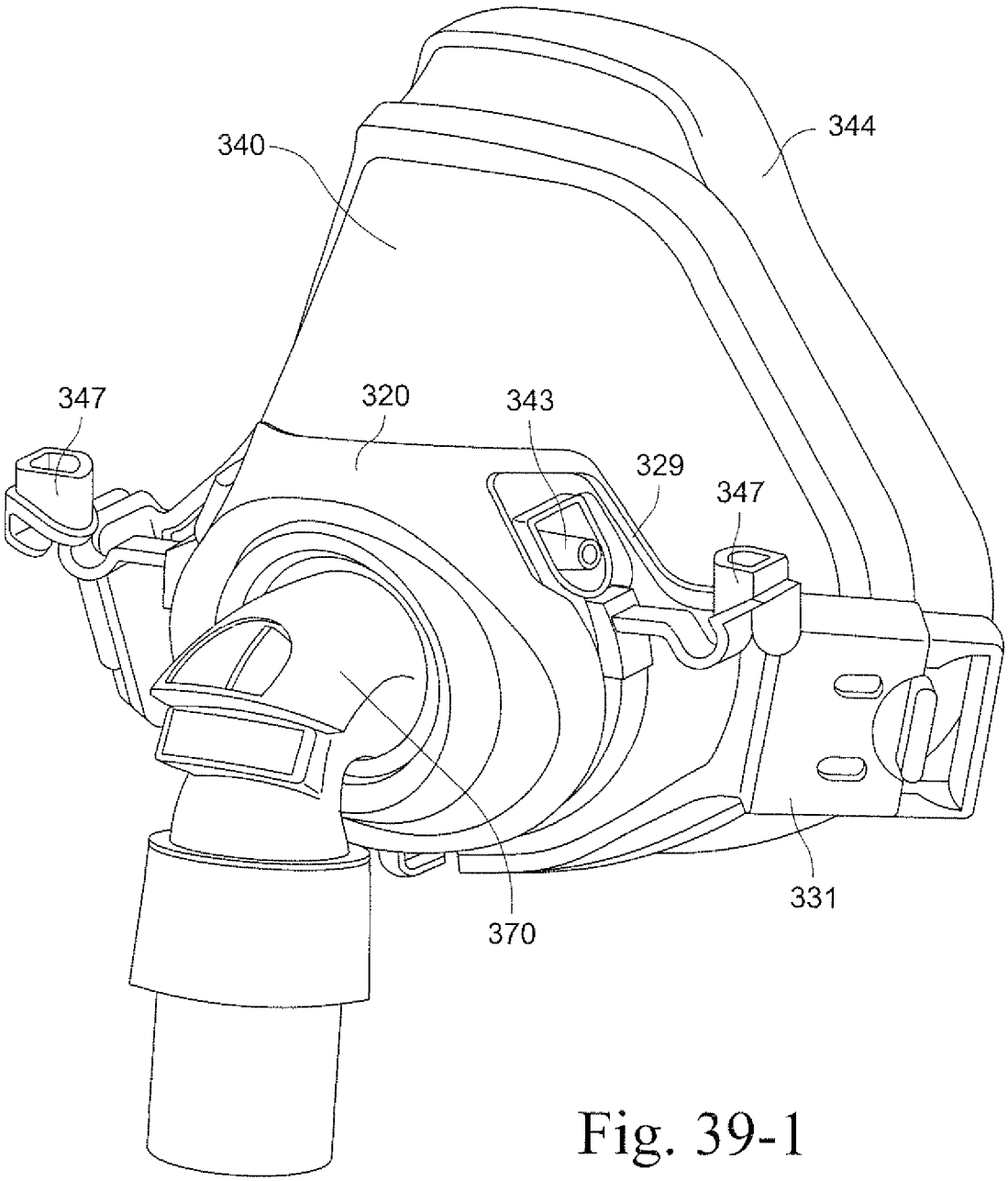

Fig. 39-1

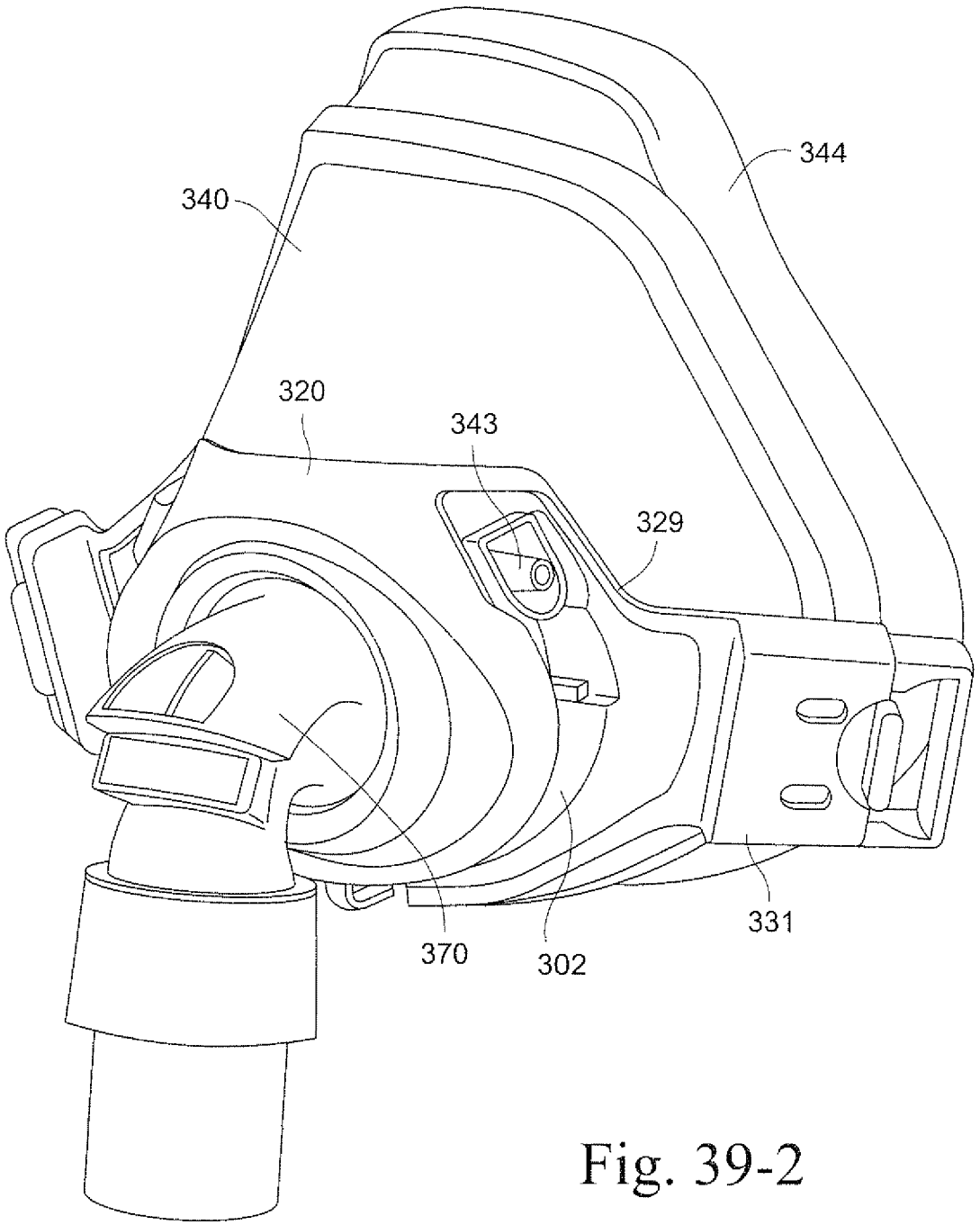

Fig. 39-2

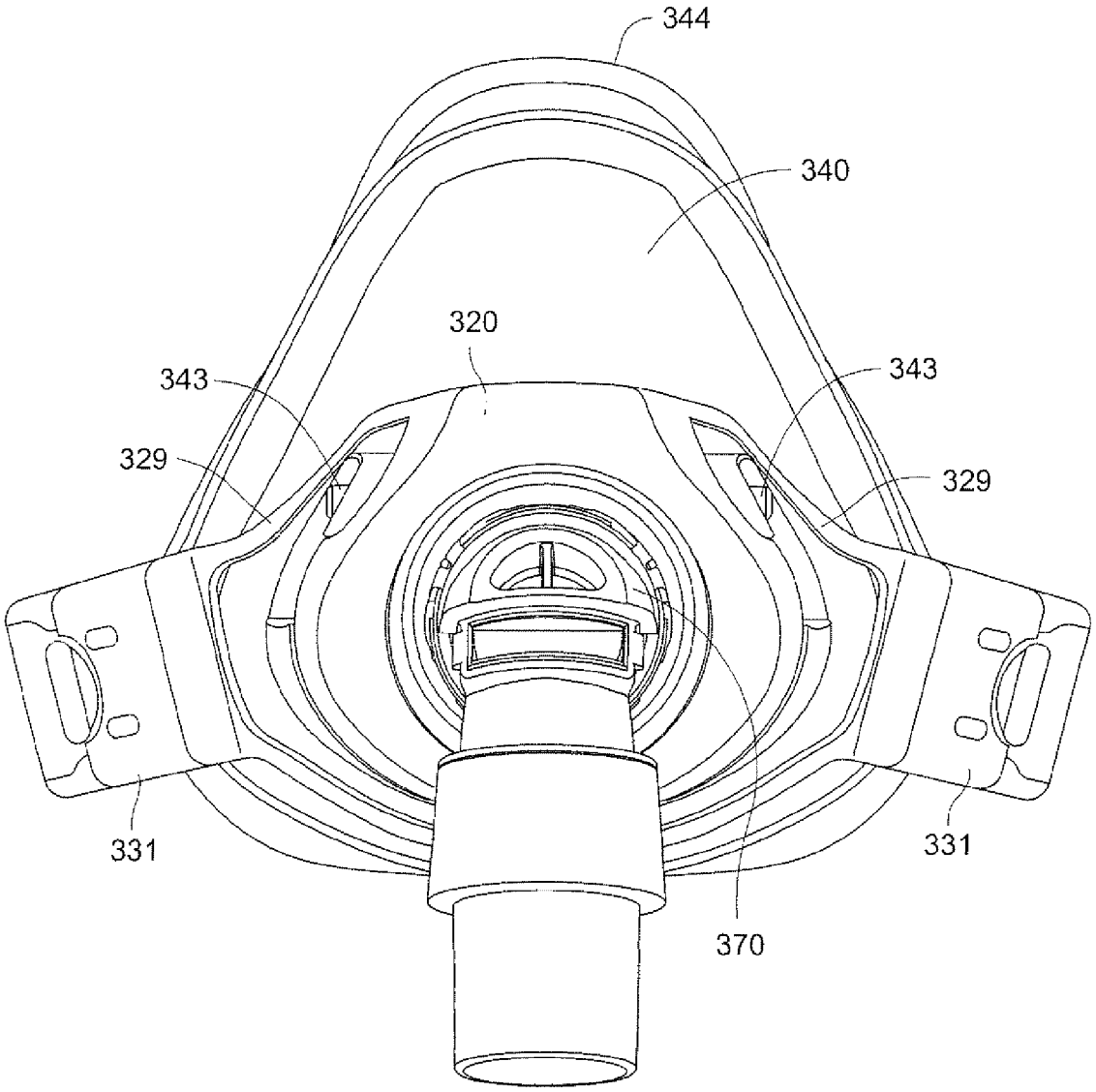

Fig. 39-3

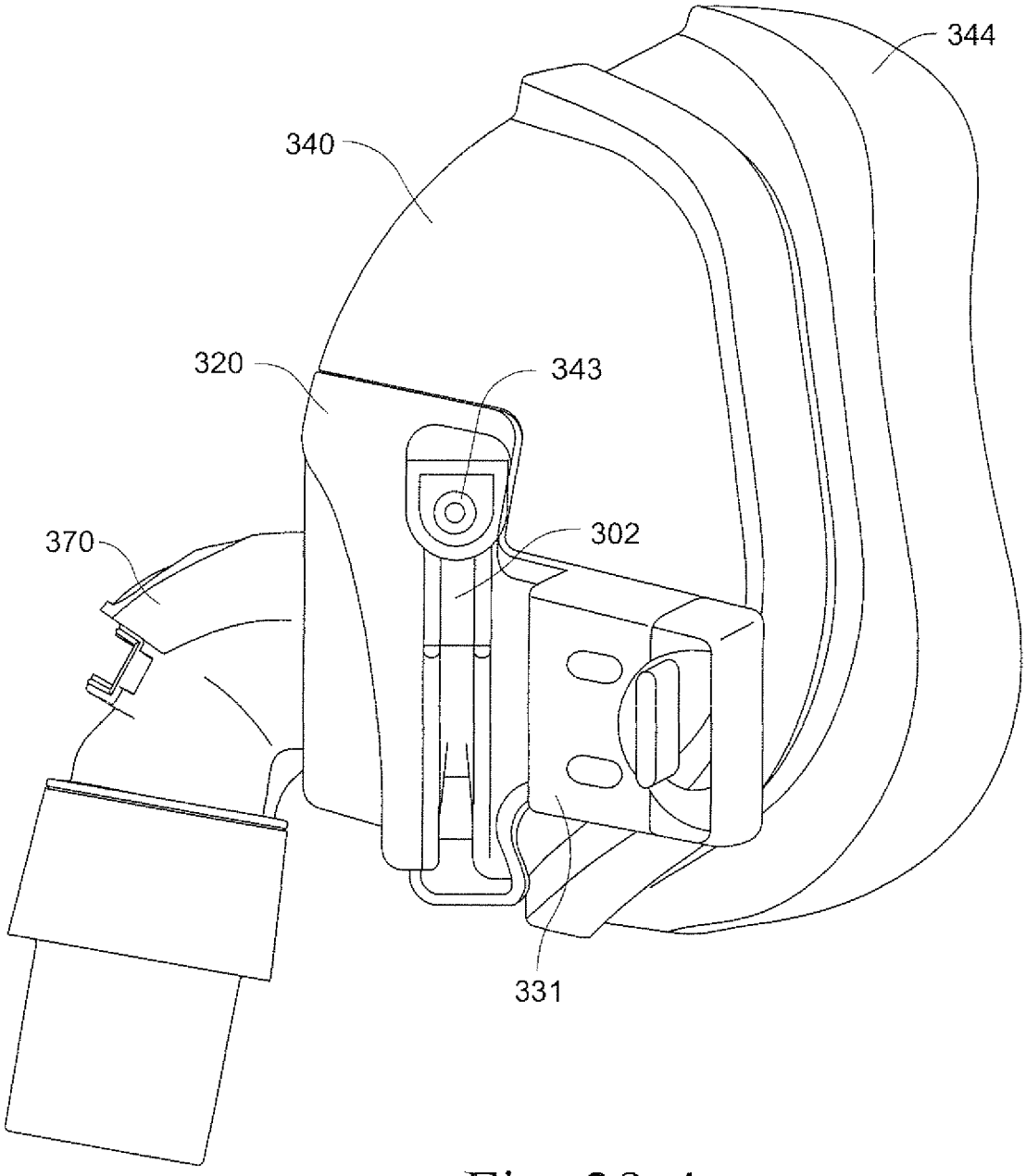

Fig. 39-4

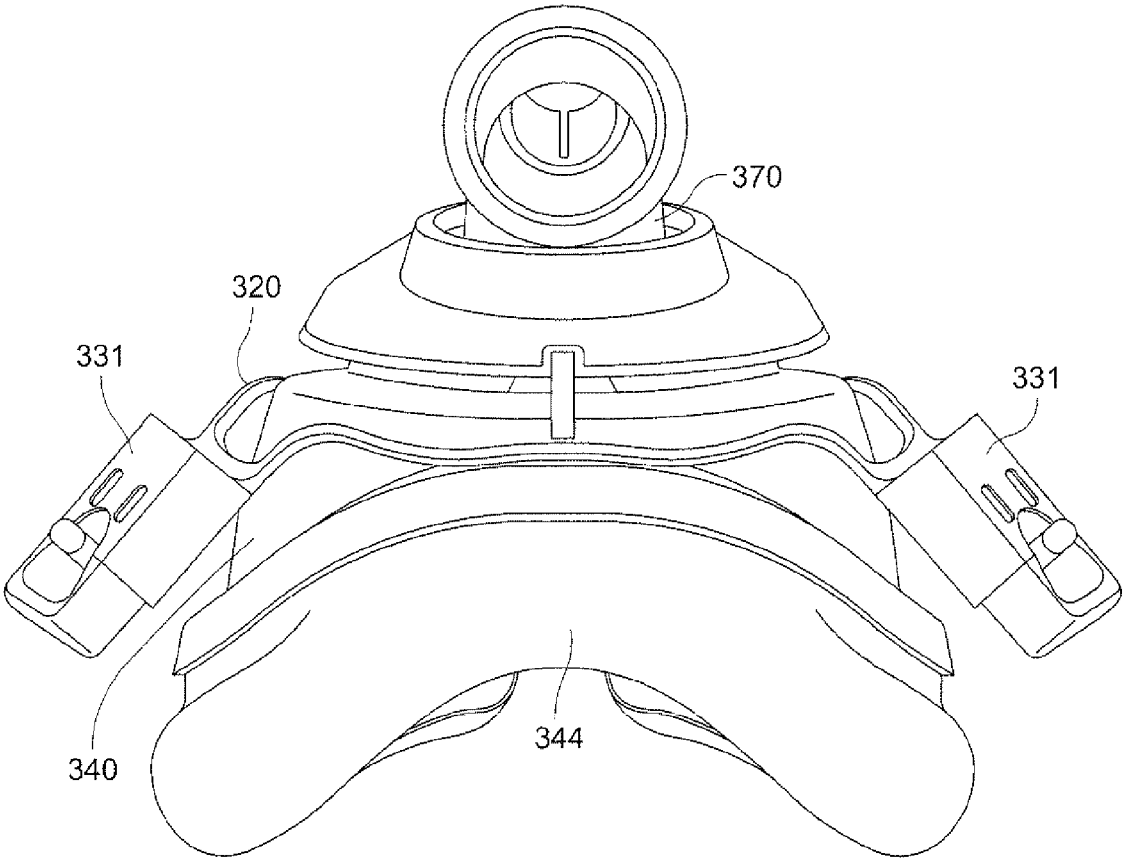

Fig. 39-5

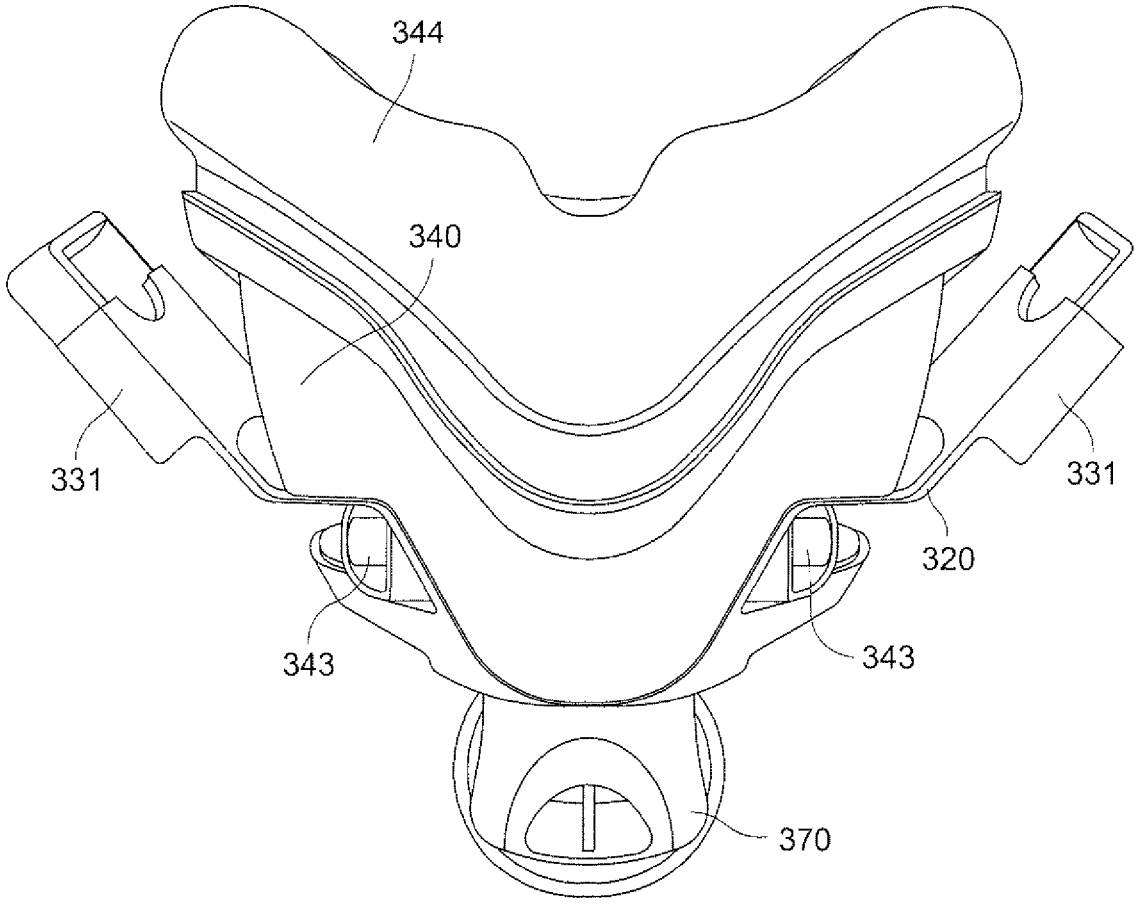

Fig. 39-6

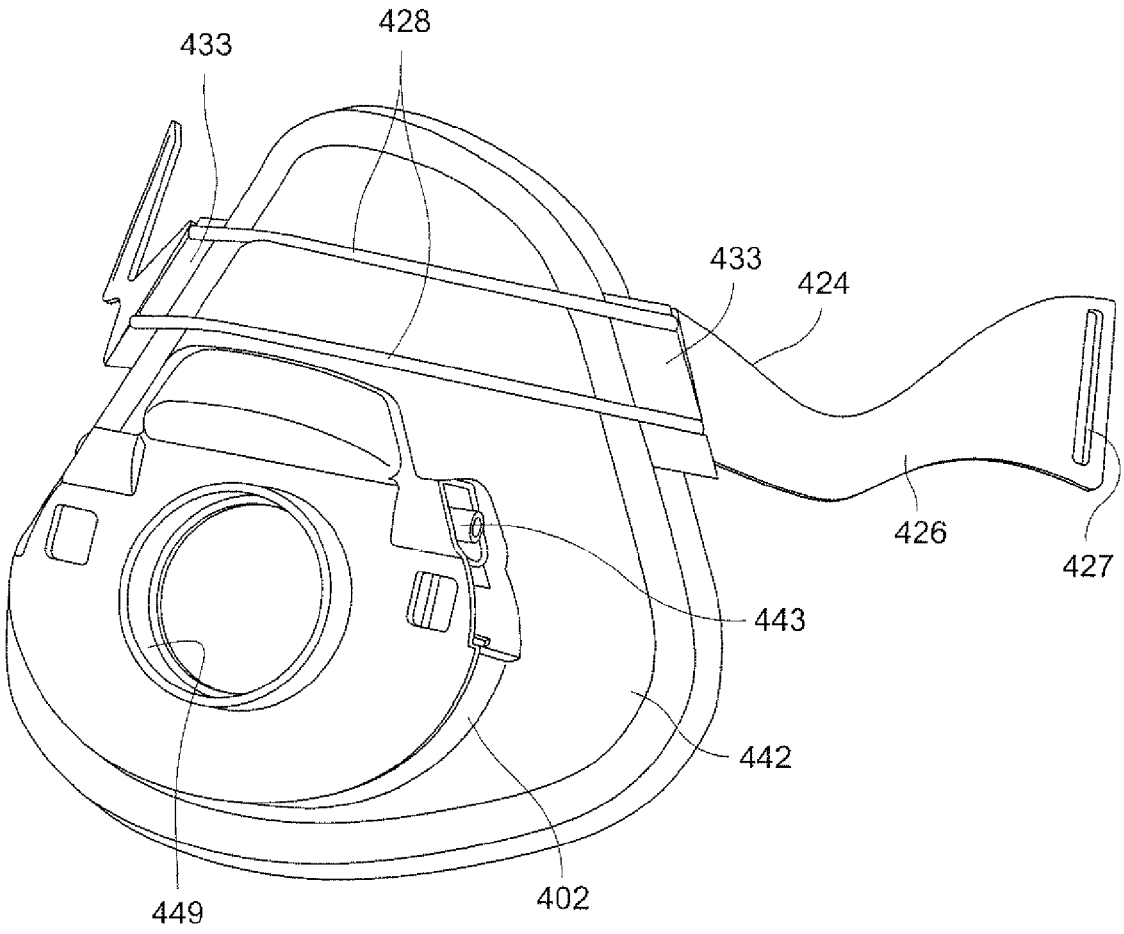

Fig. 40-1

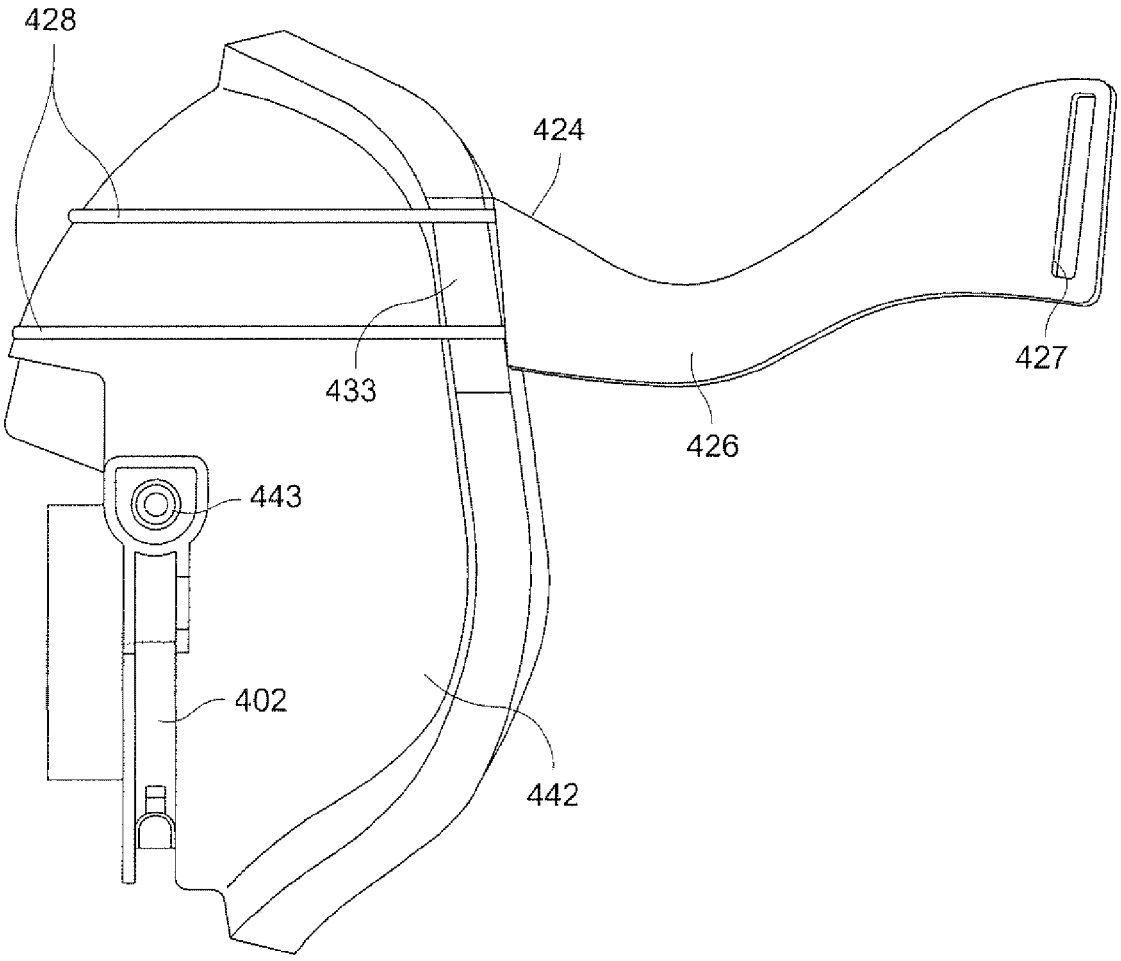

Fig. 40-2

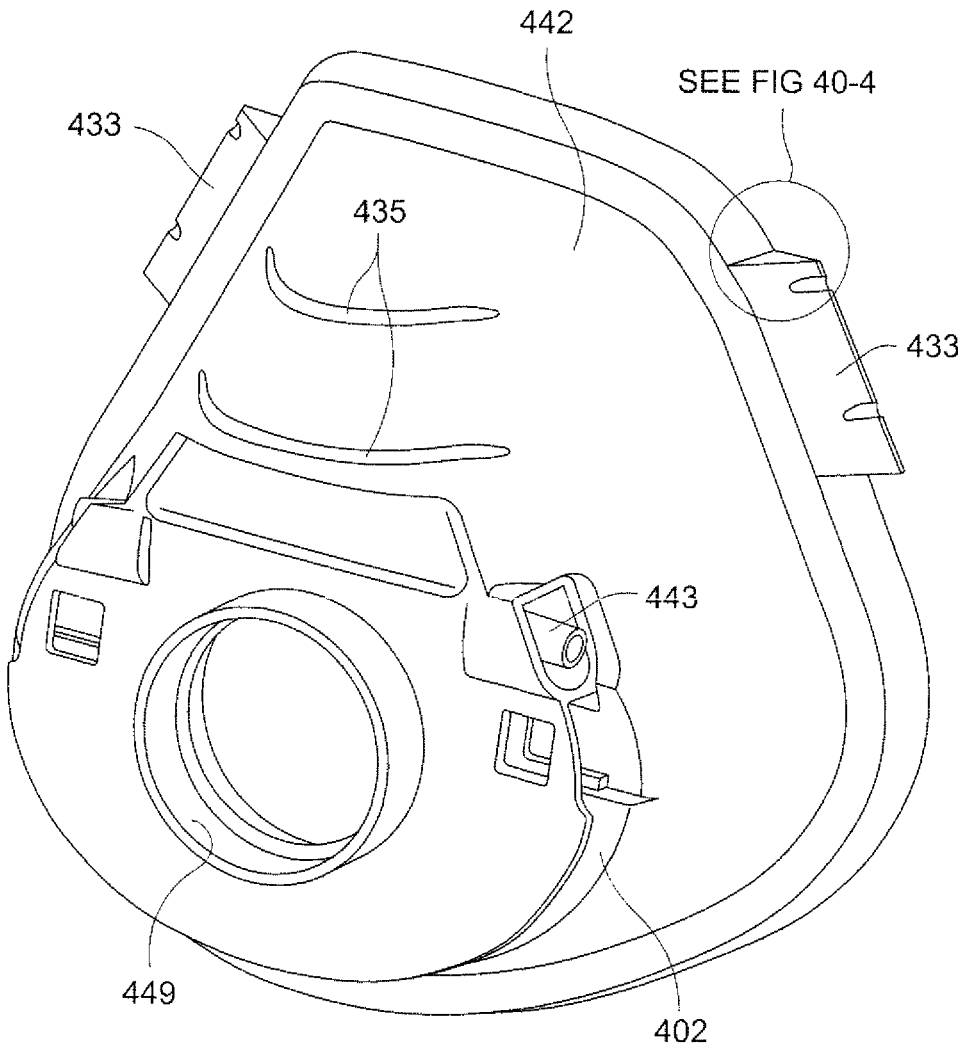

Fig. 40-3

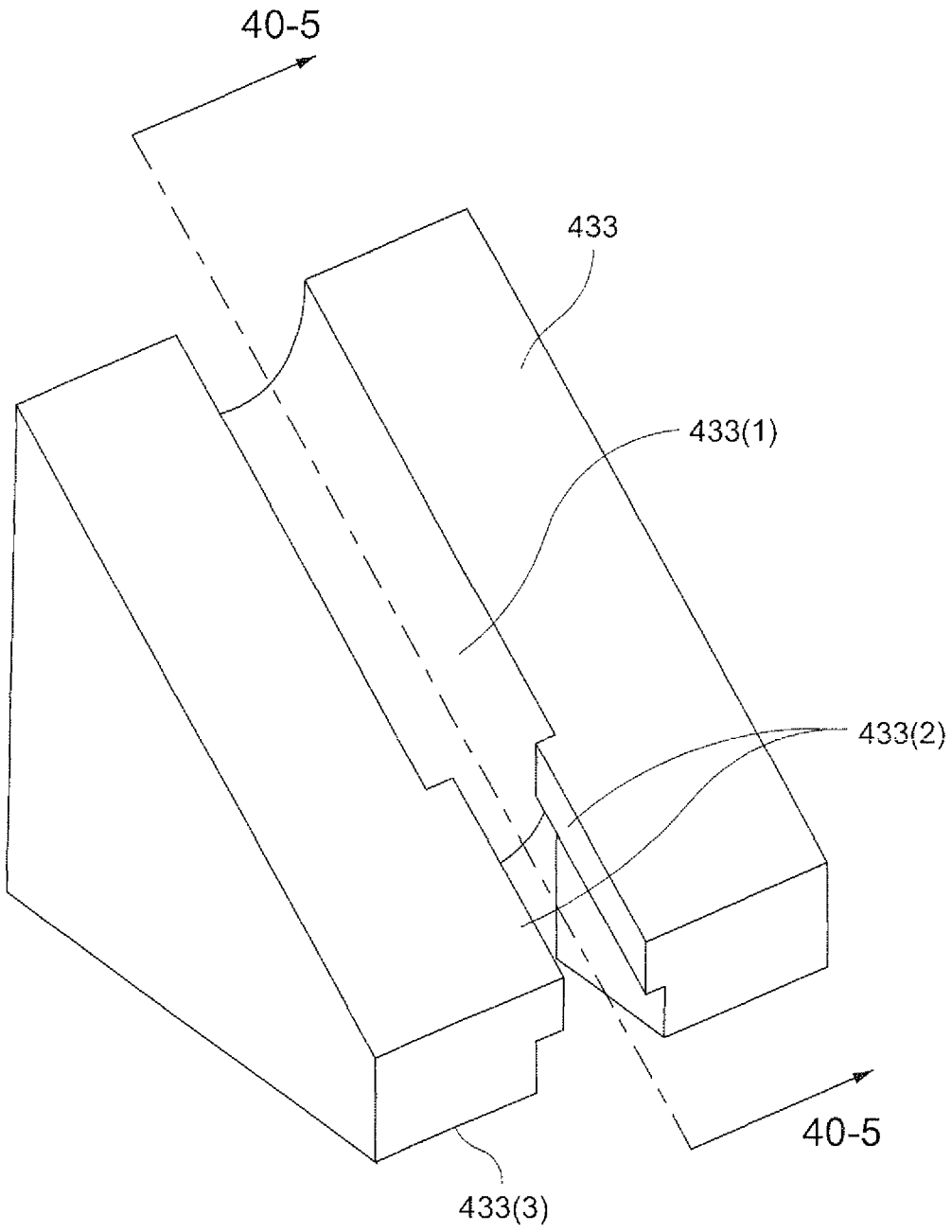

Fig. 40-4

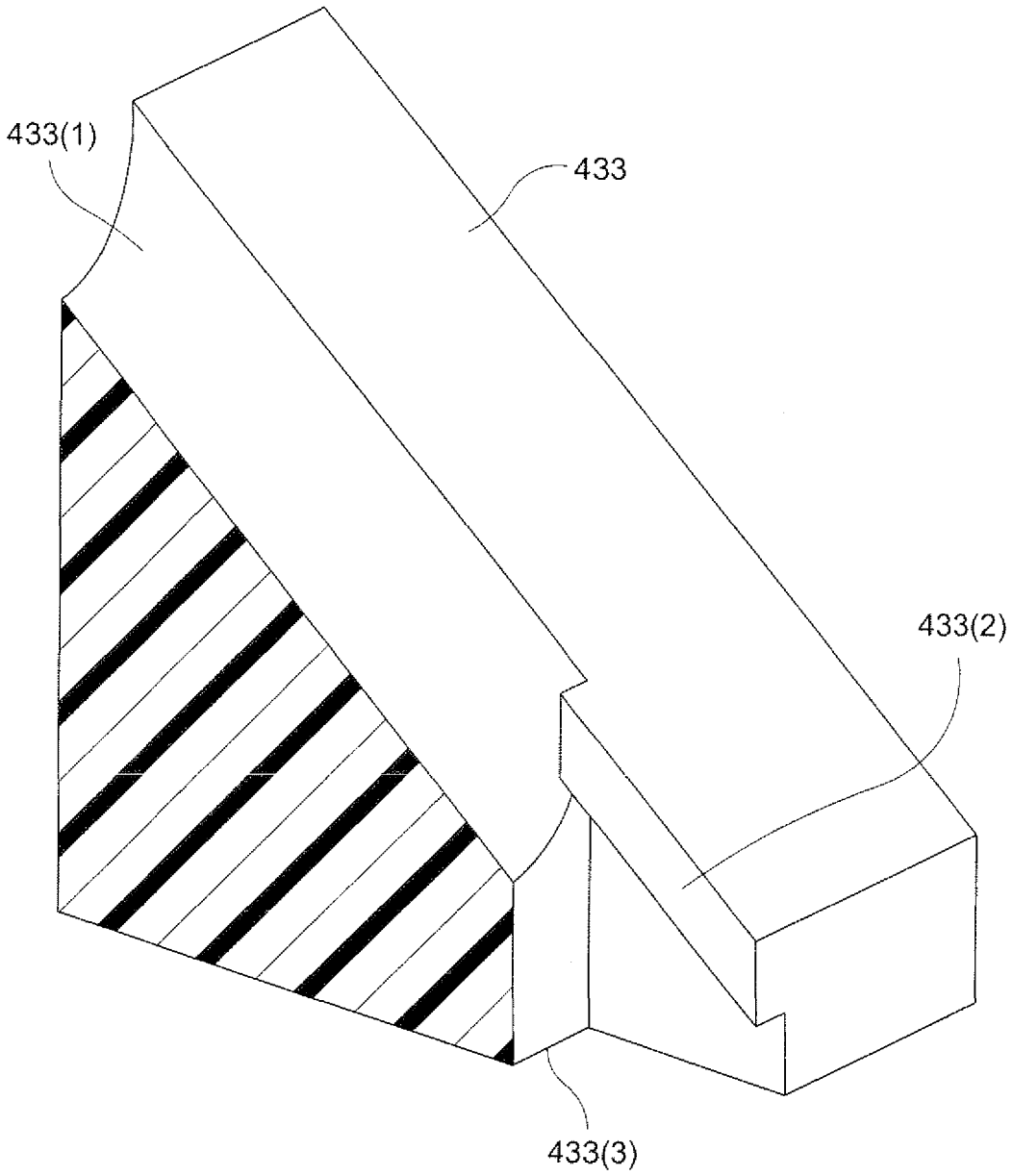

Fig. 40-5

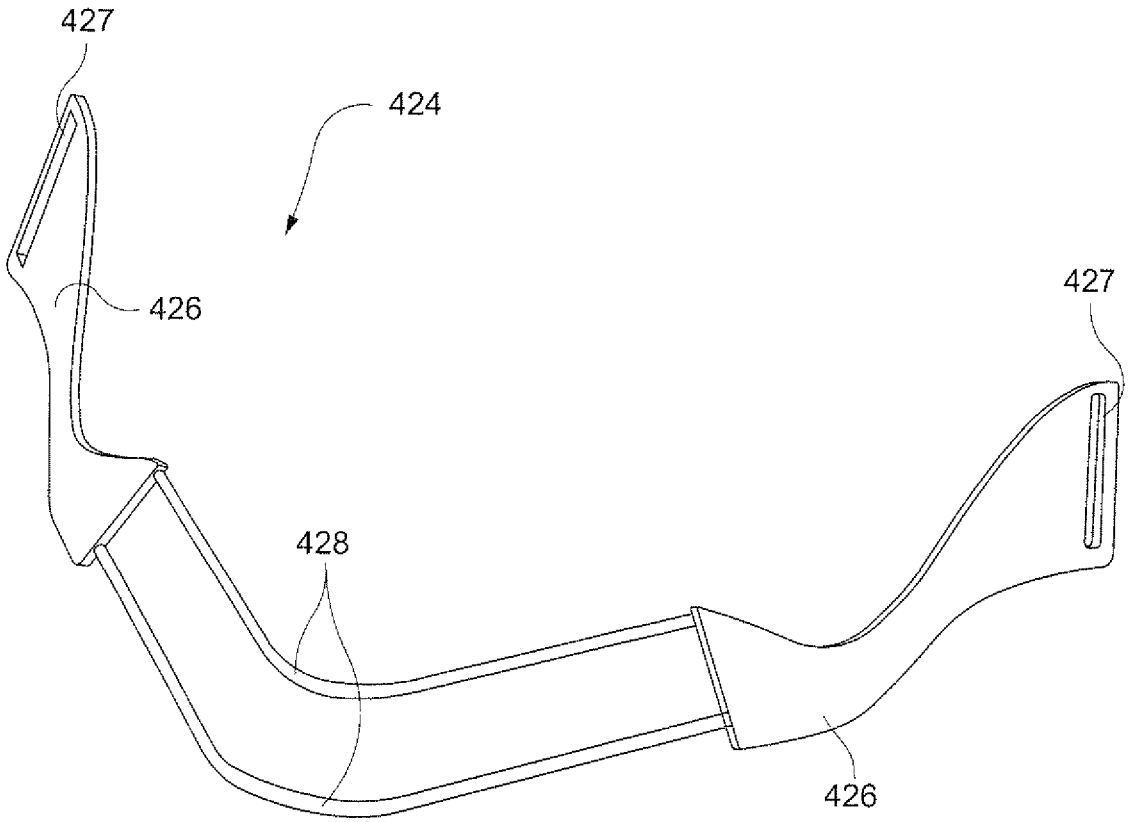

Fig. 40-6

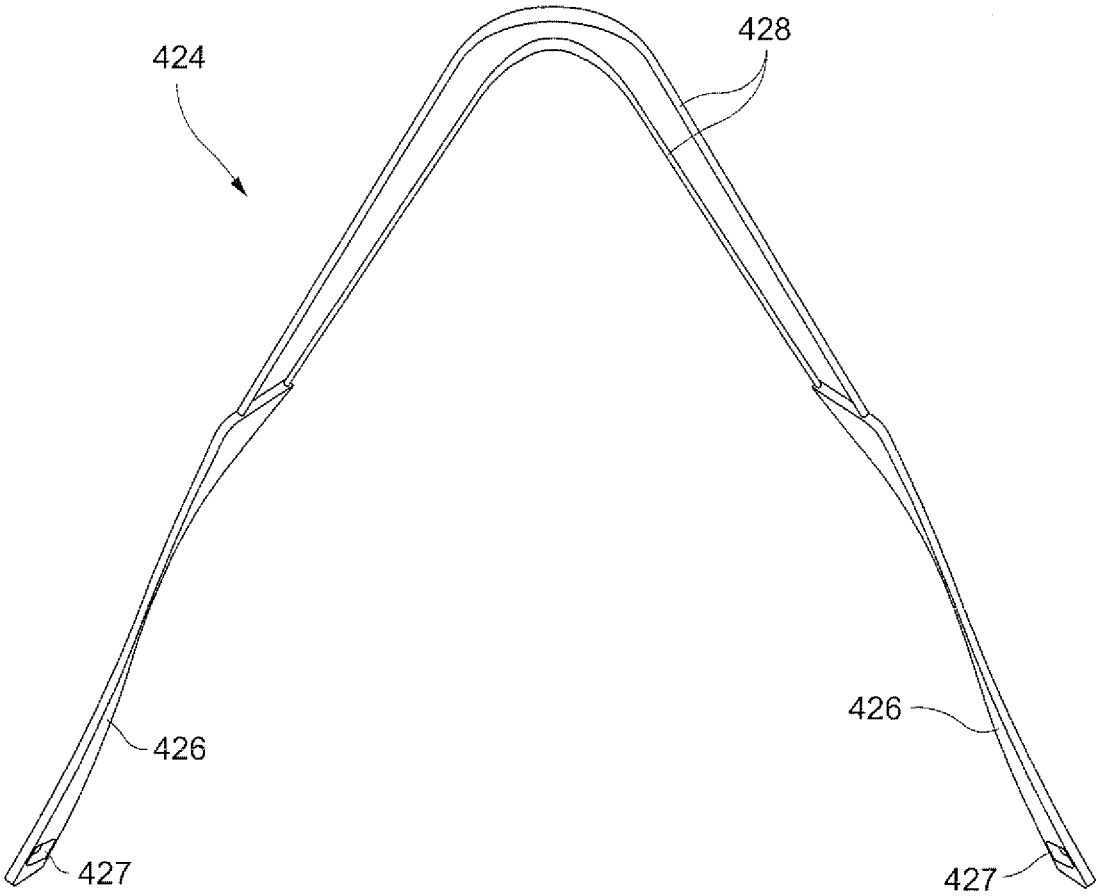

Fig. 40-7

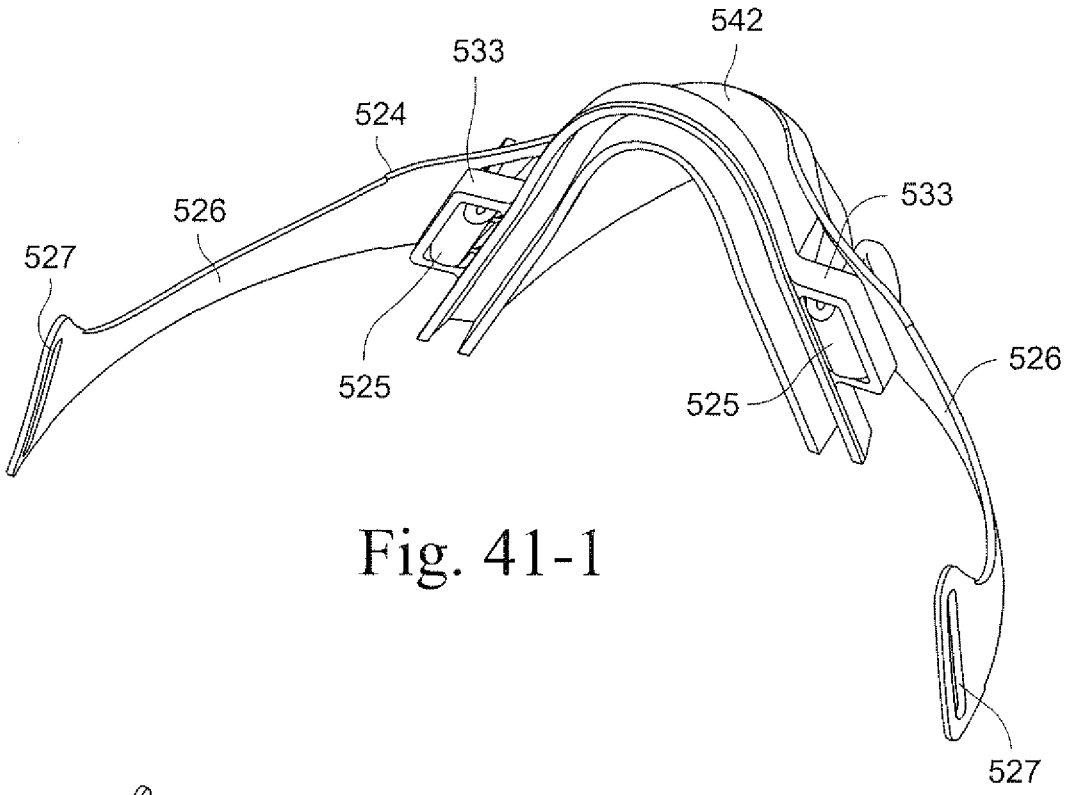

Fig. 41-1

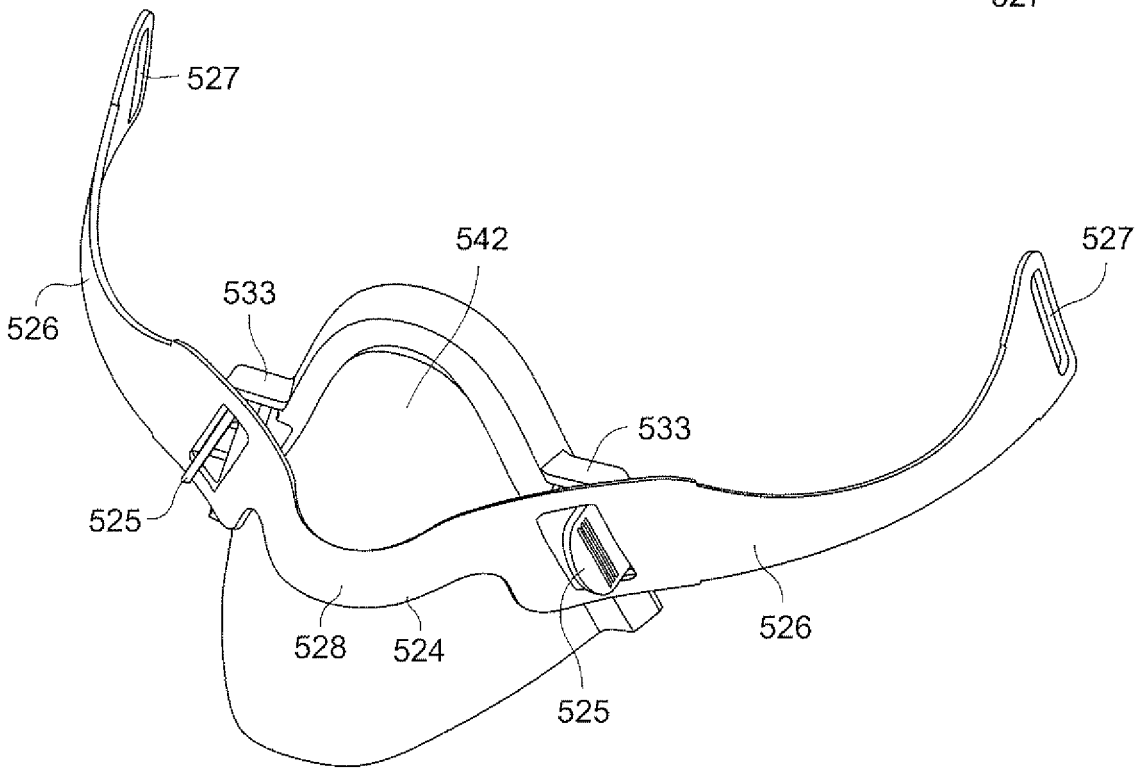

Fig. 41-2

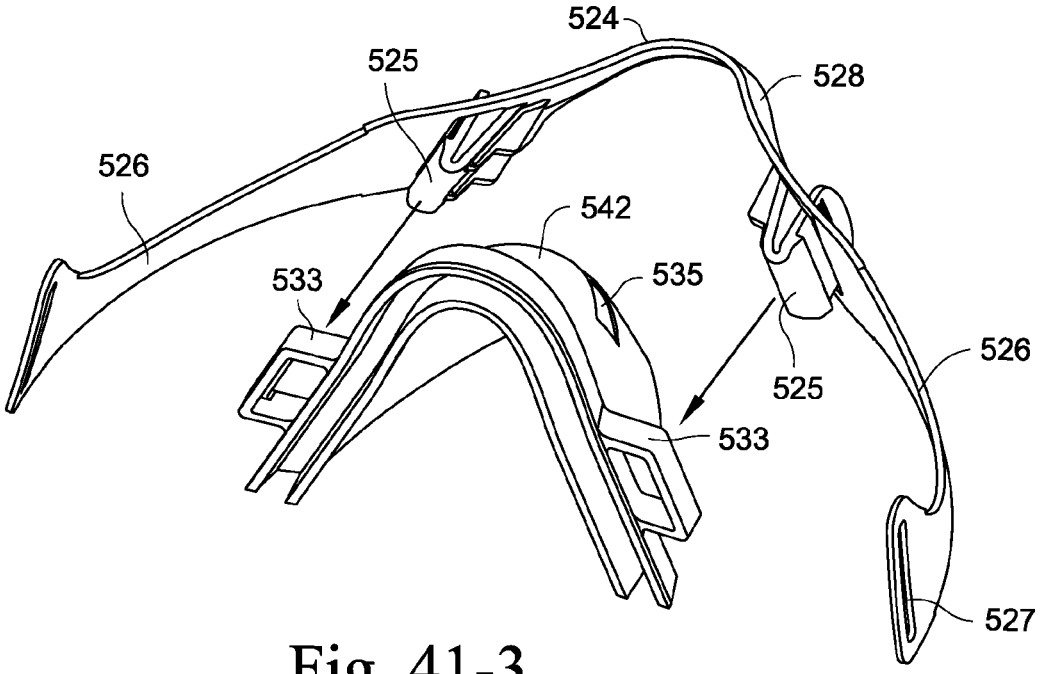

Fig. 41-3

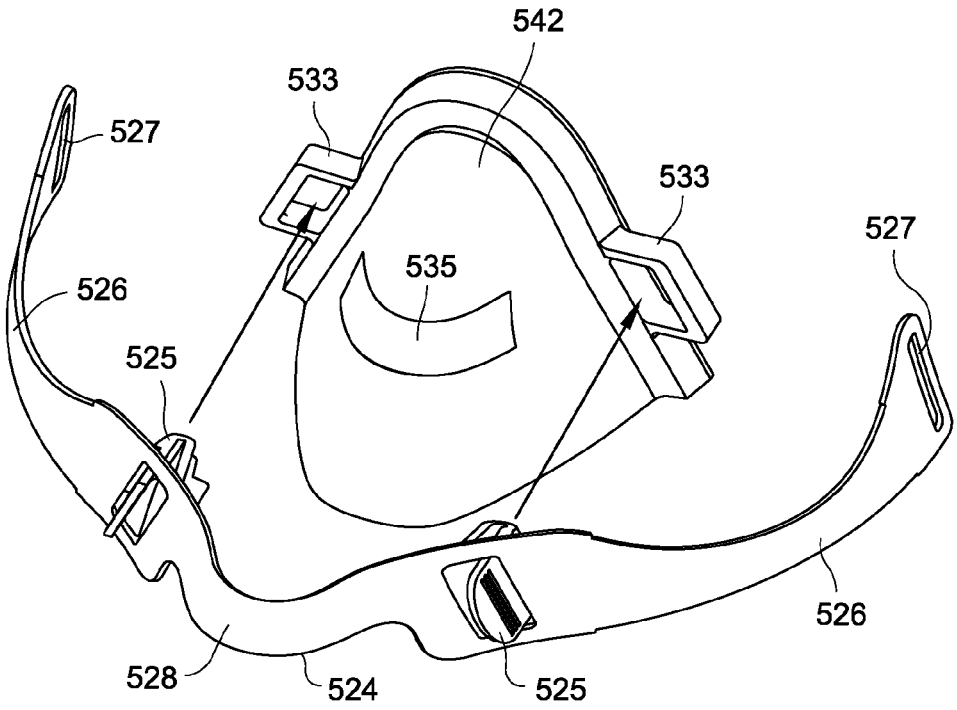

Fig. 41-4

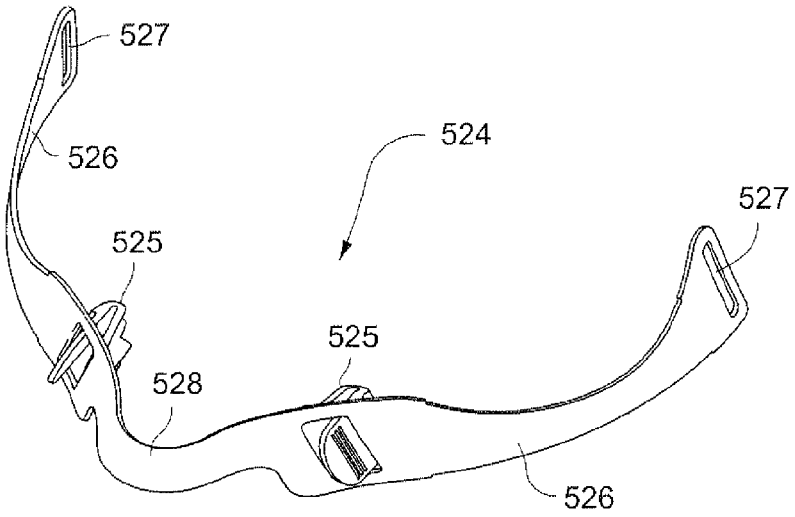

Fig. 41-5

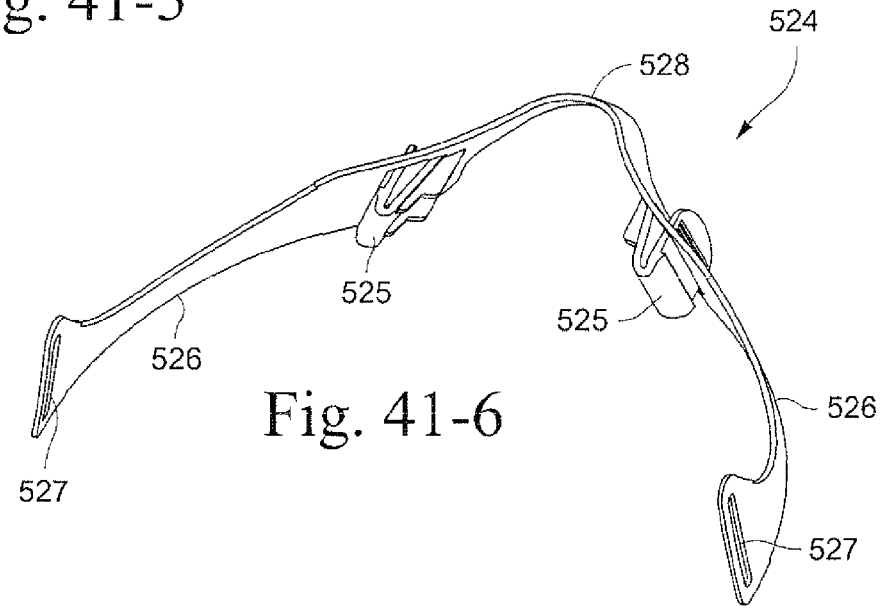

Fig. 41-6

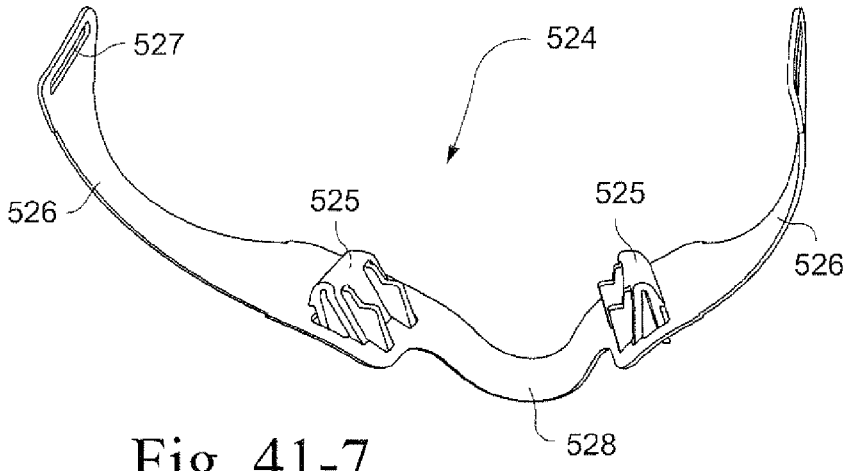

Fig. 41-7

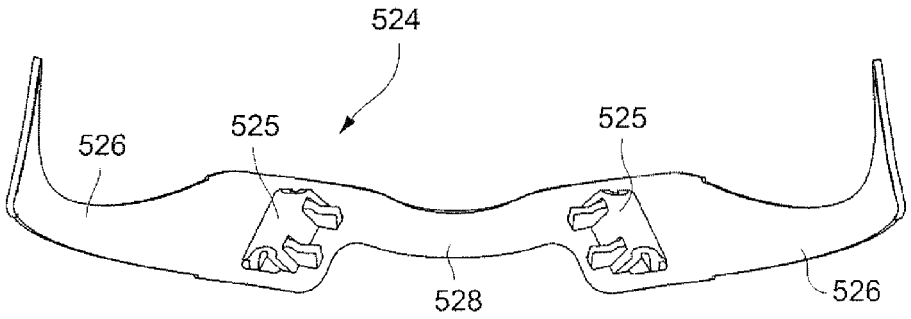

Fig. 41-8

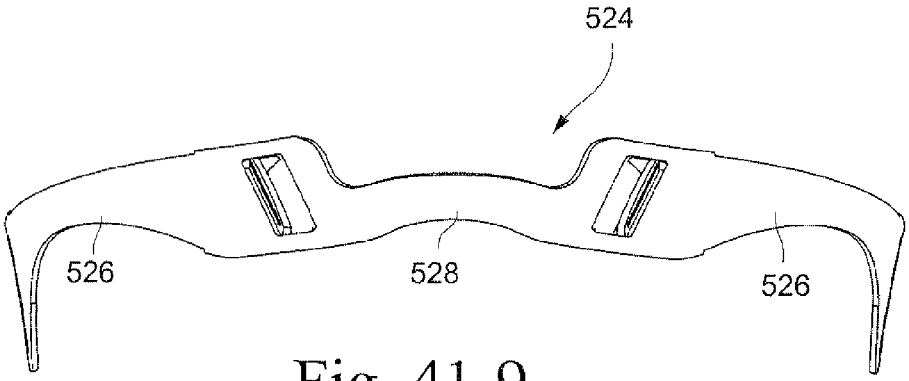

Fig. 41-9

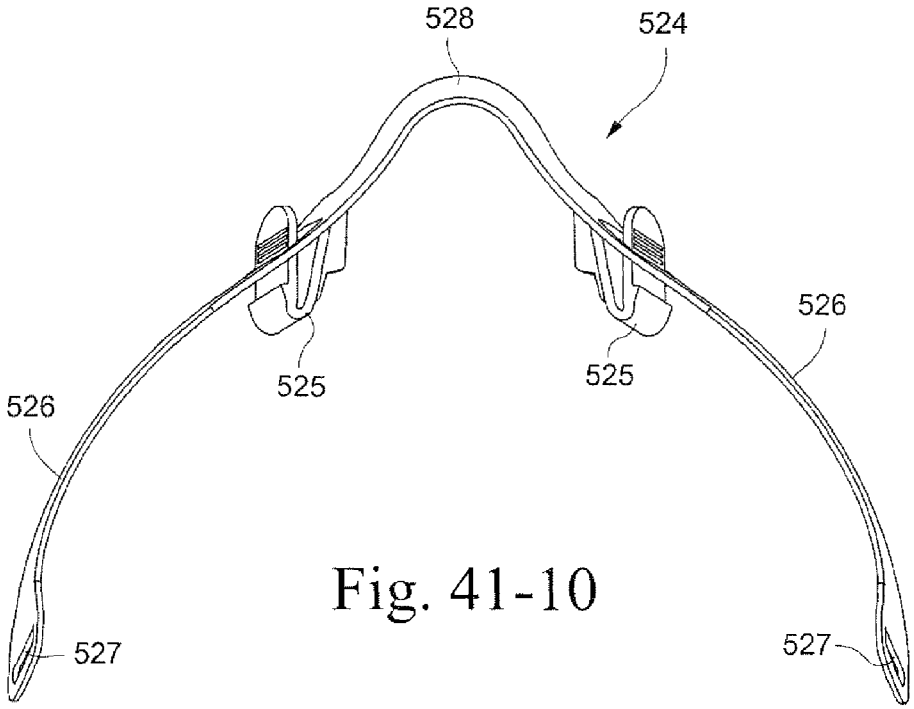

Fig. 41-10

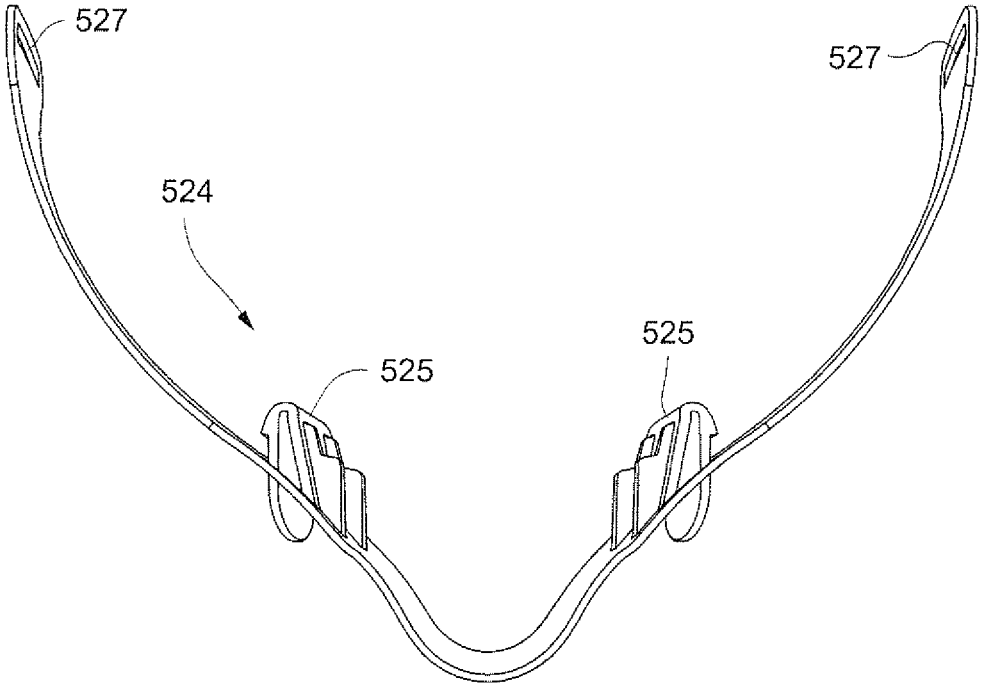

Fig. 41-11

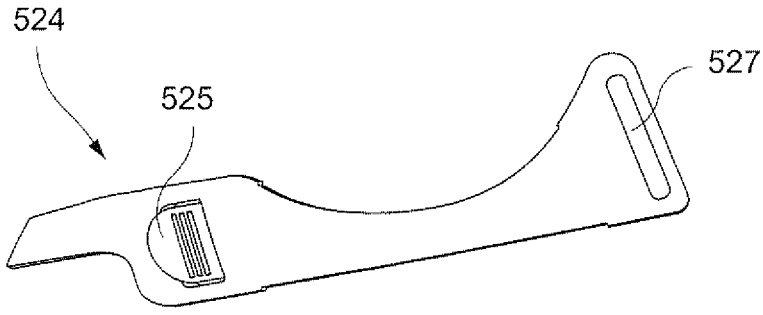

Fig. 41-12

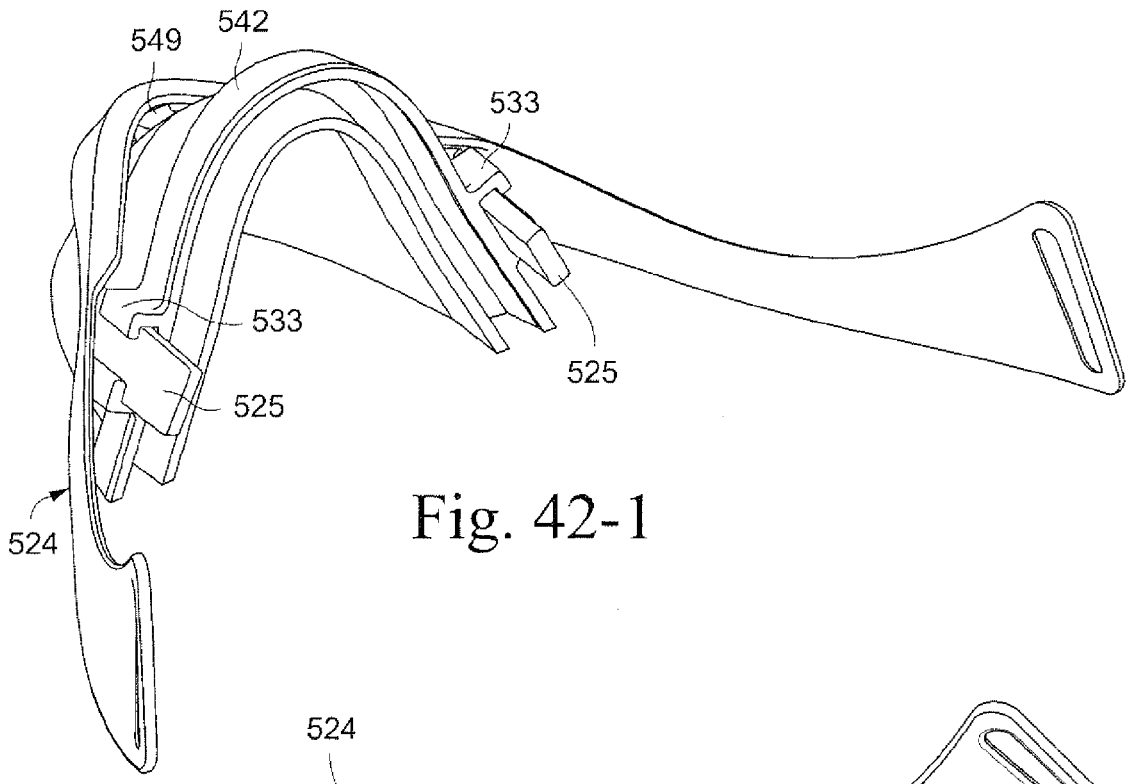

Fig. 42-1

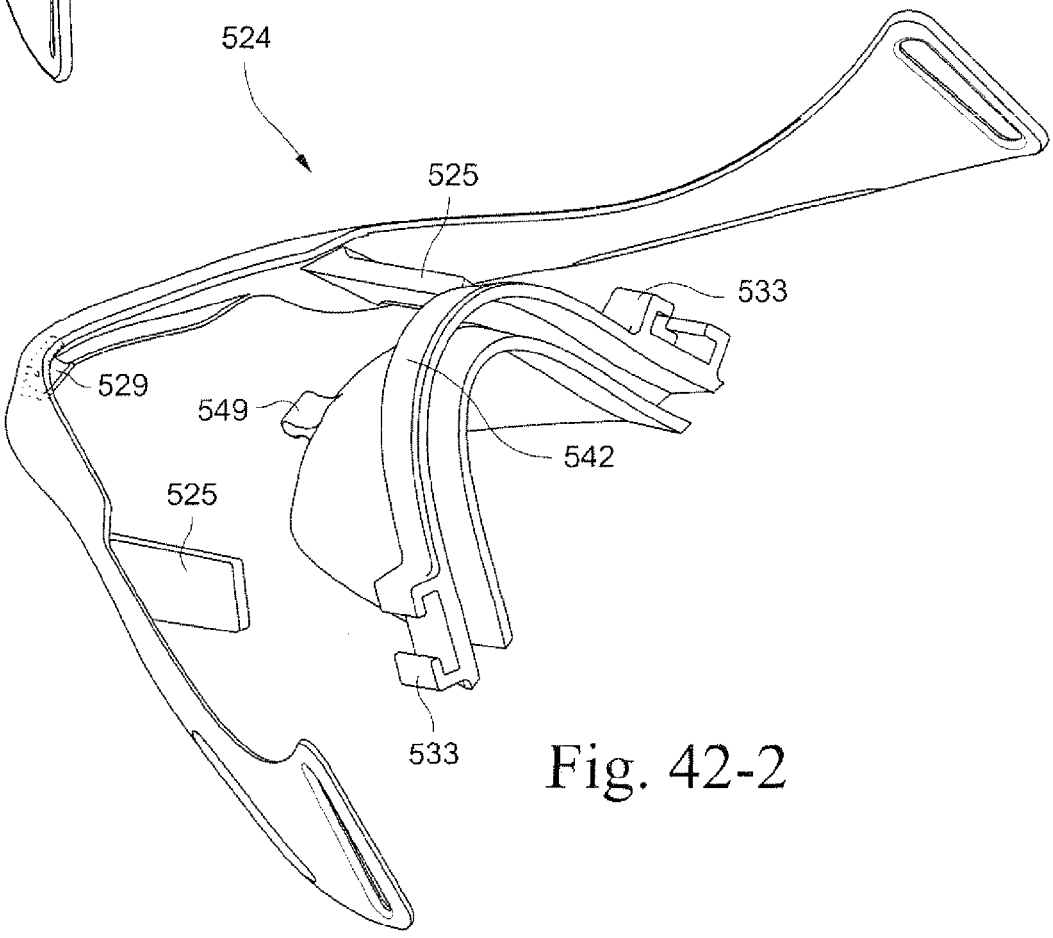

Fig. 42-2

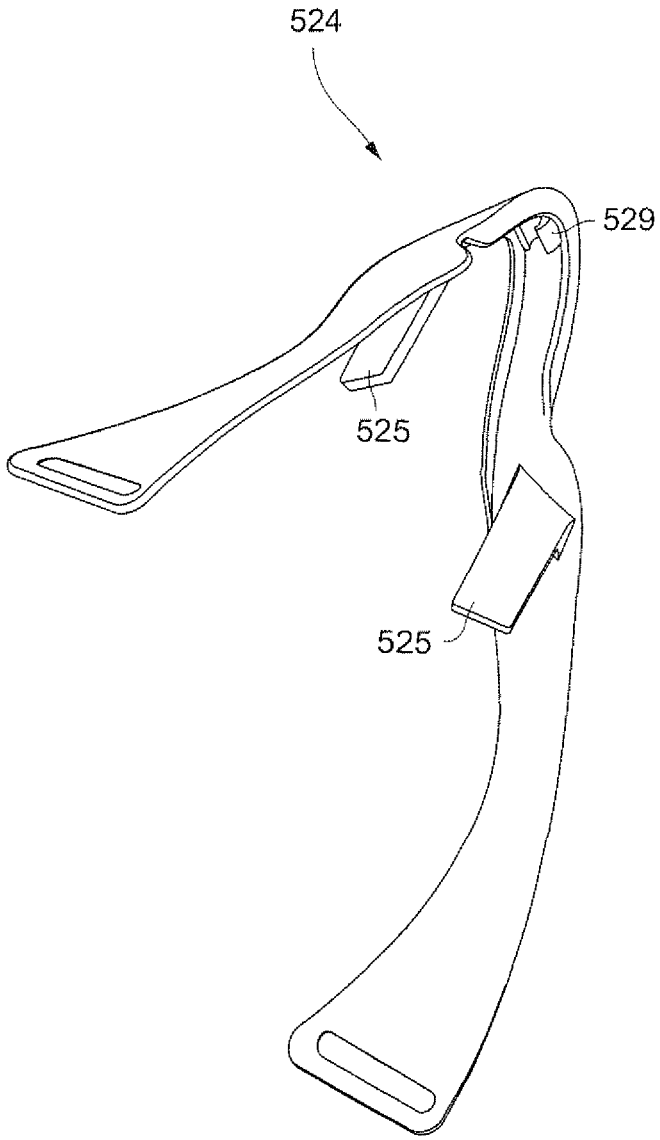

Fig. 42-3

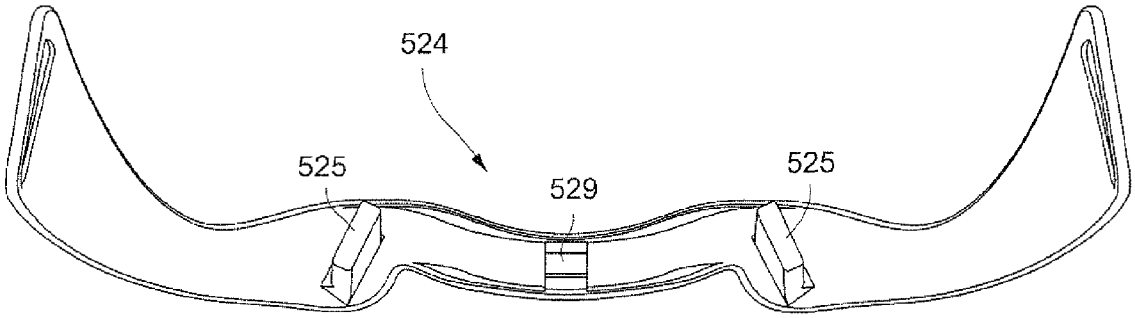

Fig. 42-4

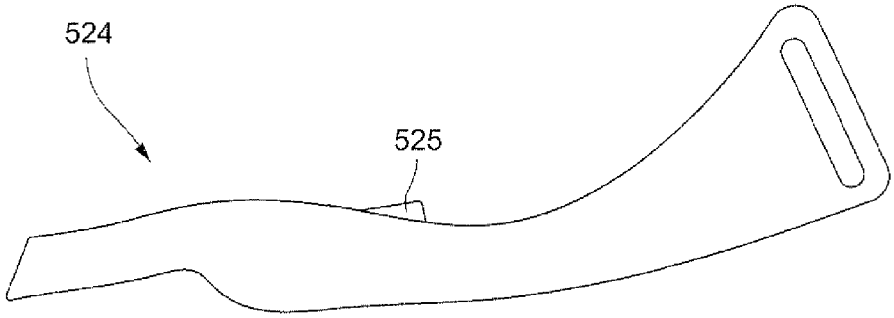

Fig. 42-5

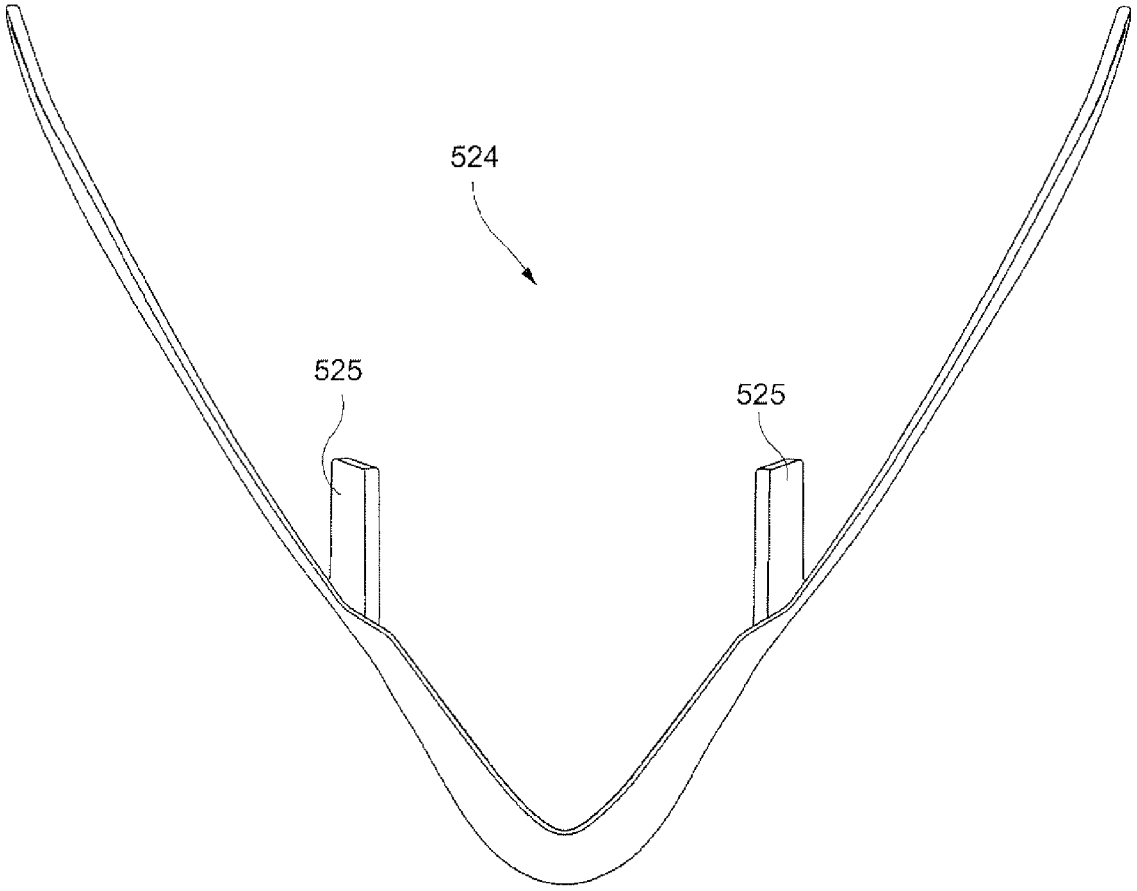

Fig. 42-6

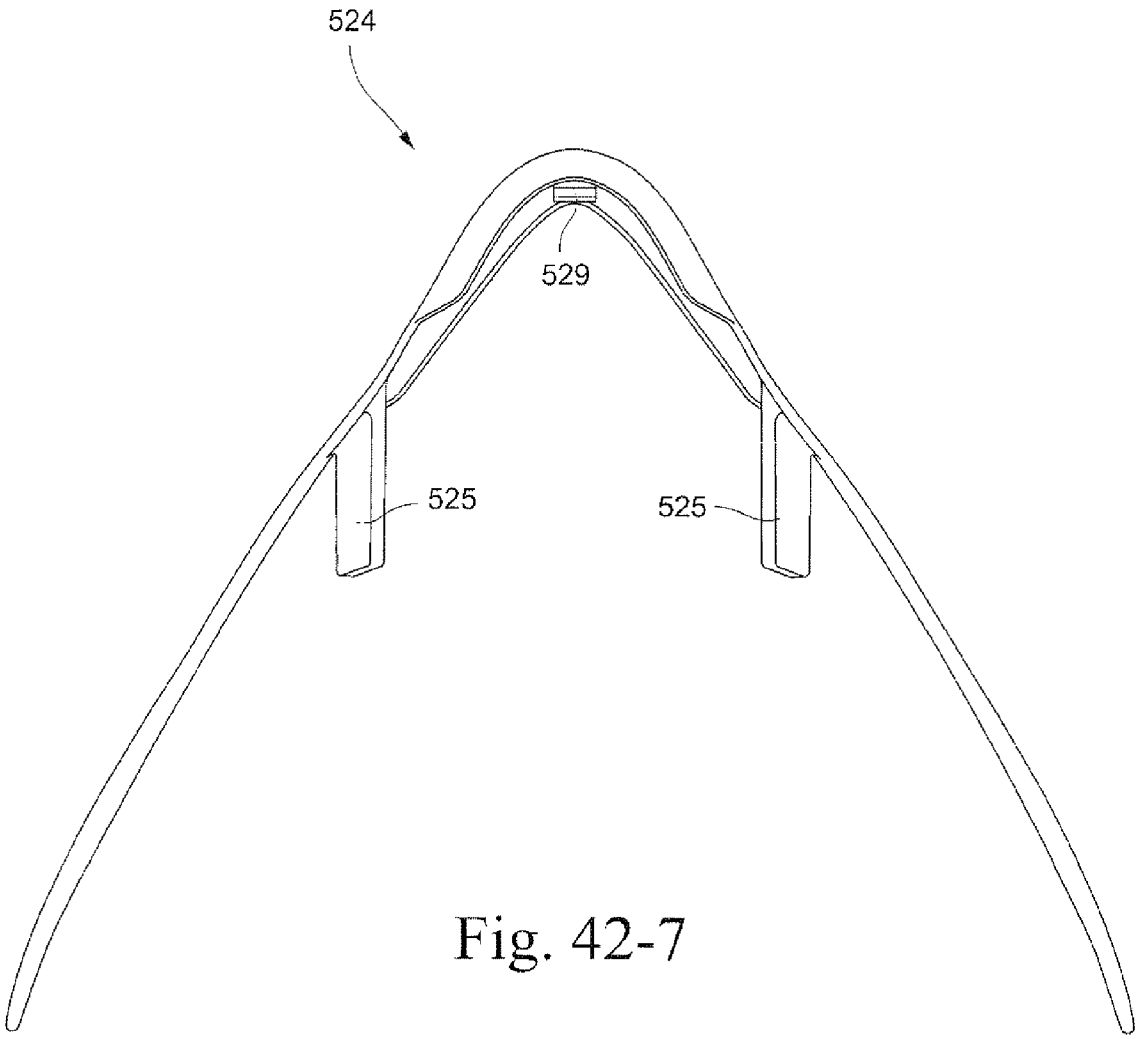

Fig. 42-7

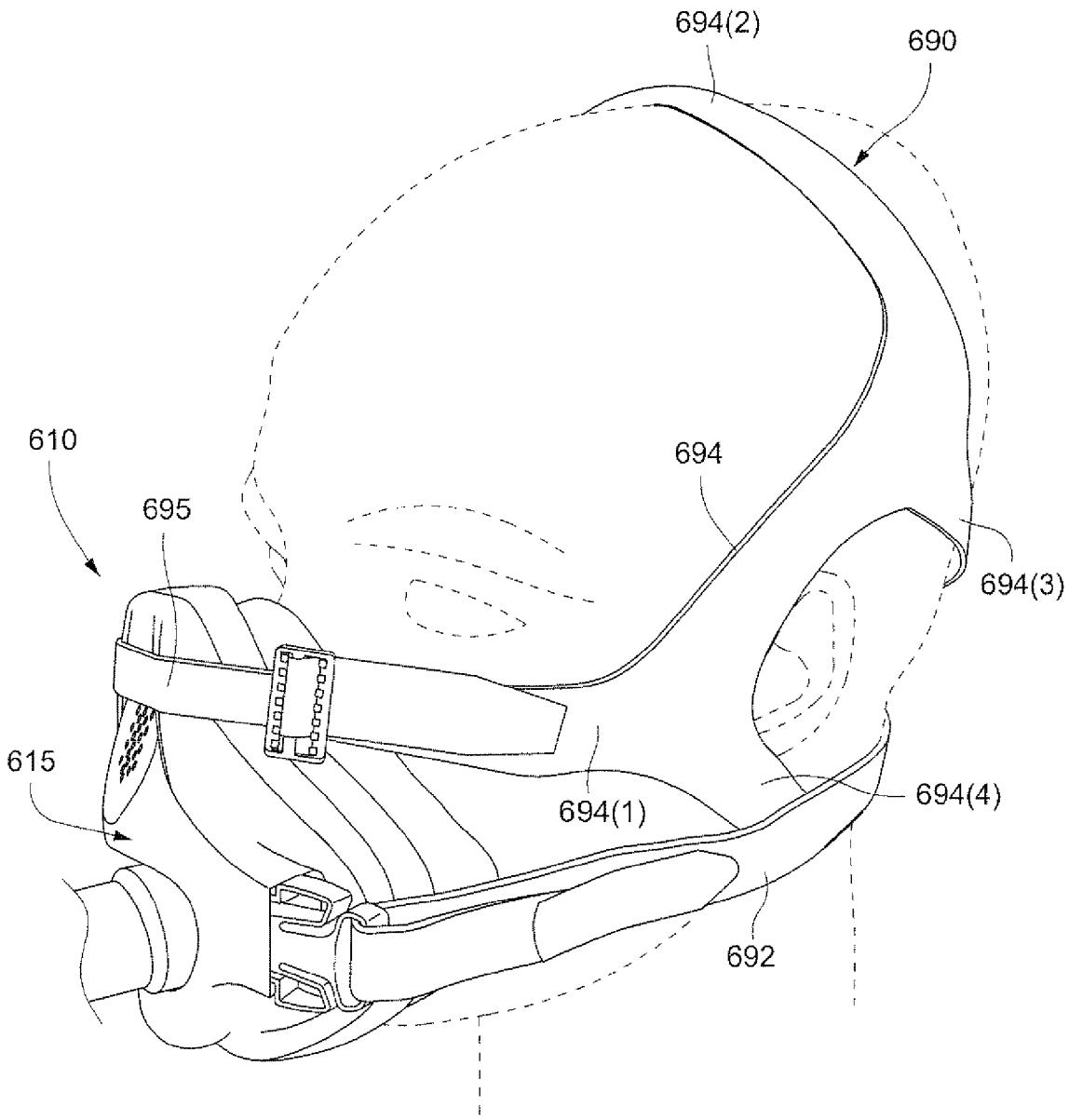

Fig. 43-1

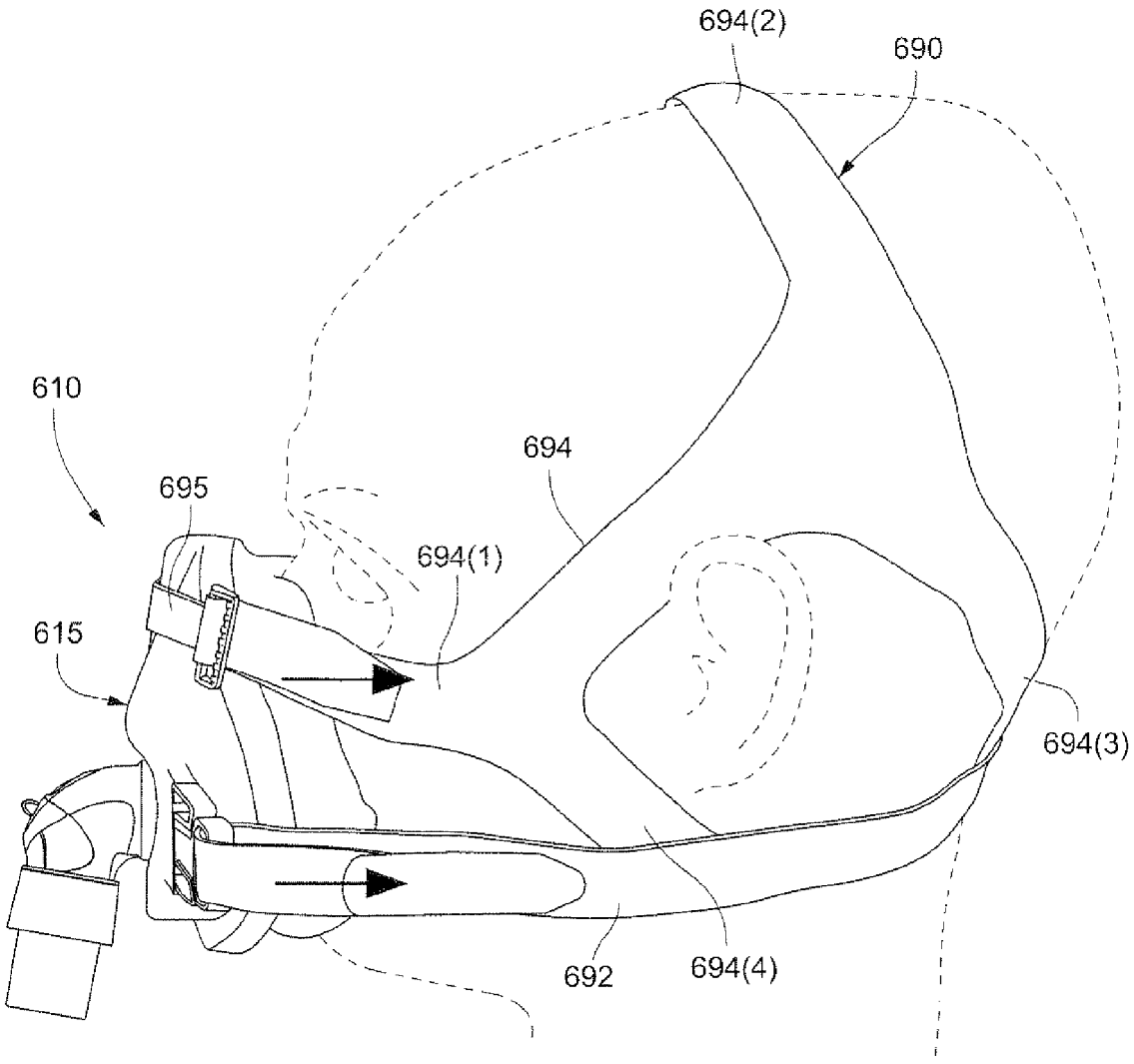

Fig. 43-2

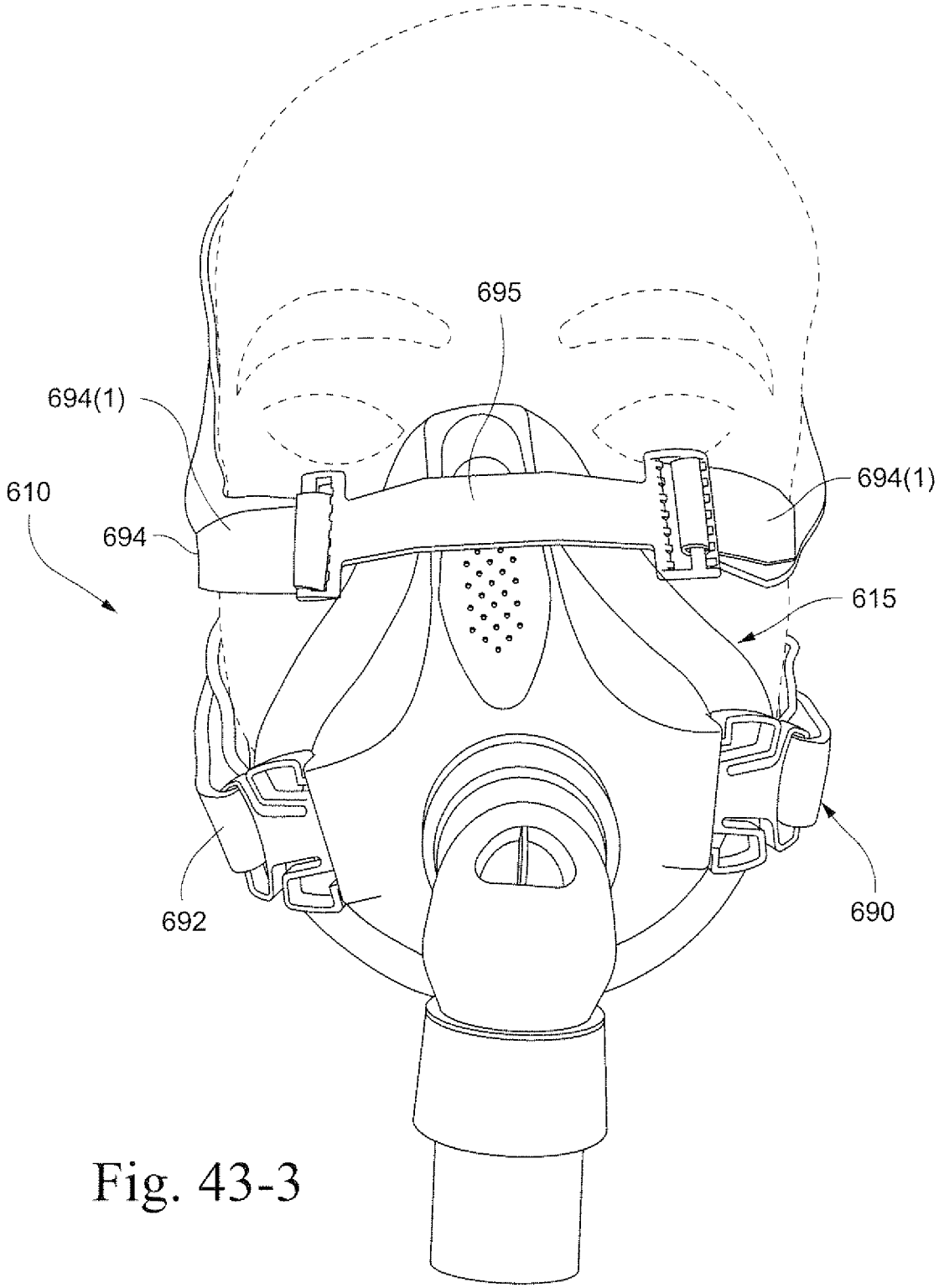

Fig. 43-3

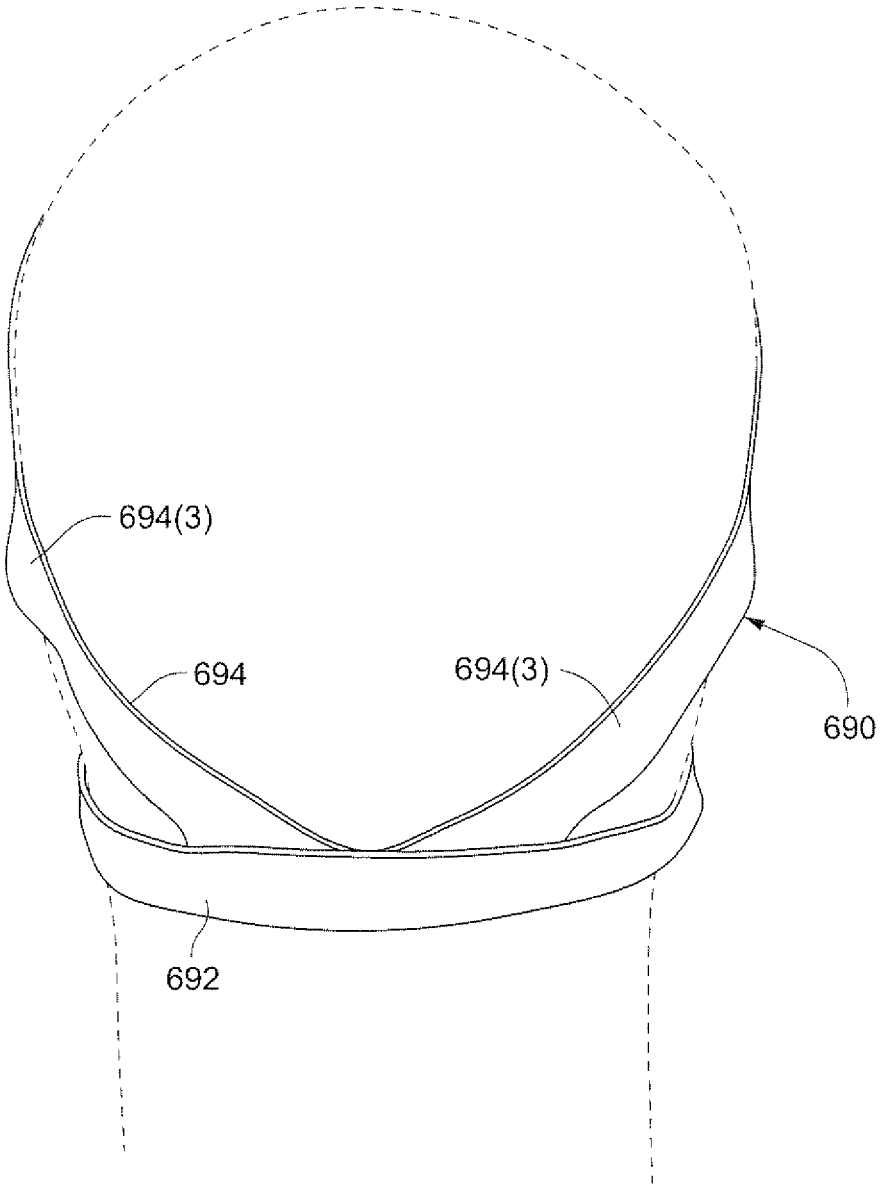

Fig. 43-4

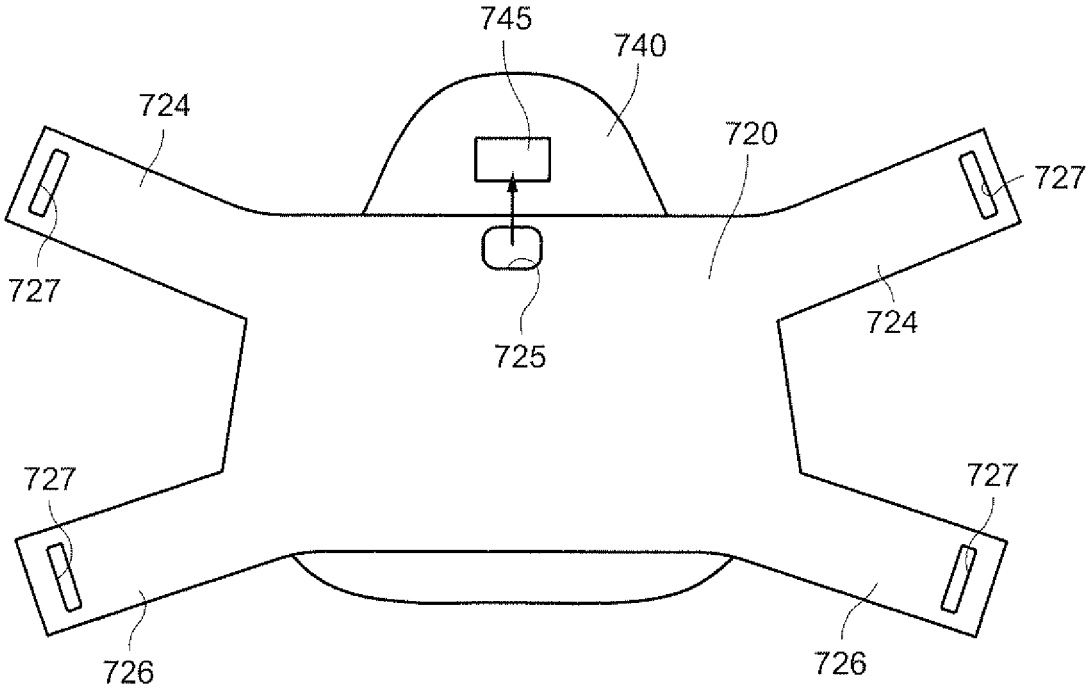
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Fig. 44

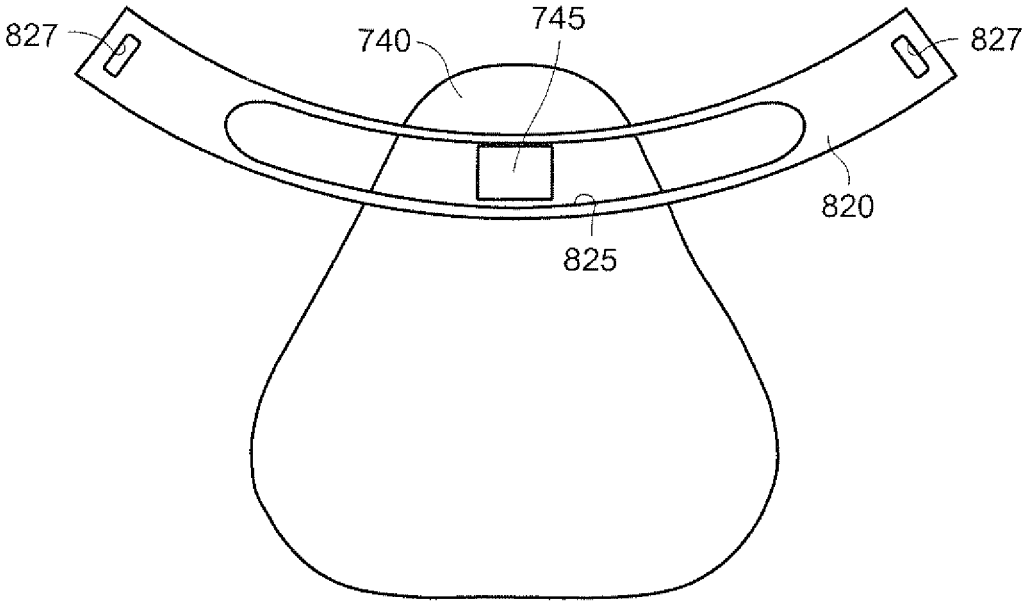
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Fig. 45

MASK SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 13/964,280, filed Aug. 12, 2013, which is a continuation of U.S. application Ser. No. 13/745,077, now U.S. Pat. No. 8,528,561, filed on Jan. 18, 2013, which is a continuation of U.S. application Ser. No. 12/736,024, now U.S. Pat. No. 8,550,084, filed on Sep. 2, 2010, which is the U.S. National Stage of PCT/AU2009/000241, filed Feb. 27, 2009, which claims benefit to U.S. Provisional Application Nos. 61/064,406, filed Mar. 4, 2008, 61/071,893, filed May 23, 2008, and 61/136,617, filed Sep. 19, 2008, each of which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

The present invention relates to a mask system used for treatment, e.g., of Sleep Disordered Breathing (SDB) with Continuous Positive Airway Pressure (CPAP) or Non-Invasive Positive Pressure Ventilation (NIPPV).

BACKGROUND OF THE INVENTION

Patient interfaces, such as a full-face or nasal mask systems, for use with blowers and flow generators in the treatment of sleep disordered breathing (SDB), typically include a soft face-contacting portion, such as a cushion, and a rigid or semi-rigid shell or frame. In use, the interface is held in a sealing position by headgear so as to enable a supply of air at positive pressure (e.g., 2-30 cm H_2O) to be delivered to the patient's airways.

One factor in the efficacy of therapy and compliance of patients with therapy is the comfort and fit of the patient interface.

The present invention provides alternative arrangements of mask systems to enhance the efficacy of therapy and compliance of patients with therapy.

SUMMARY OF THE INVENTION

One aspect of the invention relates to a mask system provided without a forehead support adapted to engage the patient's forehead.

Another aspect of the invention relates to a mask system including a frame and a shroud removably connected to the frame and adapted to attach headgear.

Another aspect of the invention relates to a mask system including a frame defining a breathing chamber, a cushion provided to the frame and adapted to form a seal with the patient's face, and a shroud provided to the frame. The shroud and the frame are co-molded with one another. The frame is constructed of a first, relatively soft, elastomeric material and the shroud is constructed of a second material that is more rigid than the frame. At least a portion of the frame includes a concertina section having a plurality of folds. Each of the folds has a side wall with the side walls of the folds becoming progressively longer away from the patient's face.

Another aspect of the invention relates to a cushion module including a frame defining a breathing chamber and a cushion adapted to form a seal with the patient's face. The frame and the cushion are co-molded with one another. The cushion is constructed of a first, relatively soft, elastomeric material and the frame is constructed of a second material that is more rigid than the cushion. At least a portion of the frame includes a concertina section.

Another aspect of the invention relates to a method for constructing a cushion module. The method includes molding a first part of the cushion module with a first, relatively soft, elastomeric material, co-molding a second part of the cushion module to the first part with a second material that is more rigid than the first material, and molding at least a portion of the second part to include a concertina section.

Another aspect of the invention relates to a shroud for a mask system including a retaining portion structured to retain a frame, a pair of upper headgear connectors each including an elongated arm and a slot at the free end of the arm adapted to receive a headgear strap, and a pair of lower headgear connectors each adapted to attach to a headgear strap, wherein the retaining portion, the upper headgear connectors, and the lower headgear connectors are integrally formed as a one piece structure.

Another aspect of the invention relates to a mask system including a frame defining a breathing chamber, a cushion provided to the frame and adapted to form a seal with the patient's face, a shroud provided to the frame and adapted to attach headgear, and an elbow provided to the frame and adapted to be connected to an air delivery tube that delivers breathable gas to the patient. The shroud includes a retaining mechanism structured to establish a positive connection between the shroud and the frame.

Another aspect of the invention relates to a mask system including a frame defining a breathing chamber and a cushion provided to the frame. The cushion is adapted to engage at least a portion of the patient's face. The cushion includes a base wall connected to an undercushion layer and a membrane, wherein the membrane extends around the perimeter of the cushion and contacts the patient's face. The undercushion layer is positioned underneath the membrane and supports the membrane. The under cushion layer provides differential support to the membrane at predetermined regions of the face.

Another aspect of the invention relates to a mask assembly for use in medical applications having a top and bottom ends defined by its position relative to a patient's face, wherein the mask assembly is connected to a plurality of flexible straps, which are adapted to engage the patient's head. The flexible straps engage at least two elongated rigid arms integrally molded to a portion of the mask assembly, and wherein the elongated arms are molded to the mask assembly proximal to the top end of the mask assembly.

Another aspect of the invention relates to a mask assembly for use in medical applications including a main body connected to a cushion adapted to cover nose and/or mouth and wherein the mask assembly is attached by a force substantially perpendicular towards the face and wherein the force is approximately constant along the length of the mask and is balanced by a portion of the cushion engaging the patient's cheeks.

Another aspect of the invention relates to a cushion for use with a medical mask including an outer membrane layer adapted to sealably engage a face and an undercushion layer adapted to support the membrane layer. The membrane or undercushion layer includes a surface positioned between the two layers adapted to allow the layers to slide against the respective surface.

Another aspect of the invention relates to a mask system including a frame defining a breathing chamber, a cushion provided to the frame and adapted to form a seal with the patient's face, and a releasable shroud adapted to engage a

portion of the outer surface of the frame, wherein the shroud is connected to straps to position the mask system.

Another aspect of the invention relates to a mask assembly for use in medical applications including an upper end and a lower end wherein the upper end is adapted to cover the nose and the lower end is adapted to cover the mouth of a patient. The mask assembly includes no forehead support and includes two stiffened members attached to the upper end on opposed sides of the mask assembly, and wherein the stiffened members include a general curved shape and adapted to avoid covering the patient's field of vision.

Another aspect of the invention relates to a cushion for attaching to a medical mask, wherein the cushion is flexible and includes a membrane attached to the circumference of the cushion adapted to seal against the face of a patient, and at least one undercushion adapted to support the membrane and positioned underneath the membrane to prevent collapse of the membrane, in use. The membrane is softer than the undercushion. The undercushion in the regions of nasal bridge or chin is between 0 mm and 30 mm in height as measured between the base and the tip of the undercushion.

Another aspect of the invention relates to a mask assembly for use in medical applications including an upper end and a lower end wherein the upper end is adapted to cover the nose and the lower end is adapted to cover the mouth of a patient. The mask assembly includes no forehead support and includes two stiffened members attached to the upper end on opposed sides of the mask assembly, and wherein the stiffened members include a general curved shape and adapted to avoid covering the patient's field of vision.

In an alternative embodiment, the mask system may include a headgear connector or rigidizer structured to attach to the frame with a snap-fit, mechanical interlock, friction fit, and/or grommet arrangement (e.g., constructed of rubber).

In an alternative embodiment, the mask system may include headgear having an arrangement of straps constructed of silicone and/or Breath-O-Prene™ material.

Other aspects, features, and advantages of this invention will become apparent from the following detailed description when taken in conjunction with the accompanying drawings, which are a part of this disclosure and which illustrate, by way of example, principles of this invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings facilitate an understanding of the various embodiments of this invention. In such drawings:

FIG. **1** is a front perspective view of a mask system according to an embodiment of the present invention;

FIG. **1**B is a perspective view showing the mask system of FIG. **1** with headgear positioned on a patient's head;

FIG. **1**C is a cross-sectional view through the mask system of FIG. **1**;

FIG. **1**D is another cross-sectional view through the mask system of FIG. **1**;

FIG. **1**E is a side view of the mask system of FIG. **1**;

FIG. **2** is a front perspective view showing the frame and cushion of the mask system of FIG. **1**;

FIG. **3** is an exploded perspective view of the mask system of FIG. **1** showing the frame, cushion, shroud, and elbow;

FIG. **4** is another exploded perspective view of the mask system of FIG. **1** showing the frame, cushion, and shroud;

FIG. **5** is an exploded perspective view of the mask system of FIG. **1** showing the shroud and assembled frame/cushion;

FIG. **6** is a front perspective view showing the shroud of the mask system of FIG. **1**;

FIG. **7** is a front perspective view showing the cushion of the mask system of FIG. **1**;

FIG. **8** is a cross-sectional view showing a portion of the cushion of FIG. **7**;

FIG. **8**B is a cross-sectional view through nasal bridge and chin regions of the cushion of FIG. **7**;

FIG. **9** is a plan view of headgear laid out flat according to an embodiment of the present invention;

FIG. **10** is a front perspective view of a mask system according to another embodiment of the present invention;

FIG. **11** is a front perspective view showing the frame of the mask system of FIG. **10**;

FIG. **12** is a front view showing the frame of the mask system of FIG. **10**;

FIG. **13** is a side view showing the frame of the mask system of FIG. **10**;

FIG. **14** is a front perspective view showing the shroud of the mask system of FIG. **10**;

FIG. **15** is a front view showing the shroud of the mask system of FIG. **10**;

FIG. **16** is a side view showing the shroud of the mask system of FIG. **10**;

FIG. **17** is a rear perspective view showing the shroud of the mask system of FIG. **10**;

FIGS. **18-1** to **18-2** are cross-sectional views showing in sequential relation attachment of the shroud to the frame of the mask system of FIG. **10**;

FIGS. **19-1** to **19-4** are cross-sectional views showing in sequential relation attachment of the shroud to the frame of the mask system of FIG. **10**;

FIG. **20** is a perspective view showing an alternative arrangement for attaching the shroud to the frame;

FIG. **21** is a rear perspective view showing the shroud of the mask system of FIG. **10**;

FIG. **22** is a cross-sectional view showing attachment of the shroud to the frame of the mask system of FIG. **10**;

FIG. **23** is a cross-sectional view showing attachment of the shroud, frame, and elbow of the mask system of FIG. **10**;

FIG. **24** is a cross-sectional view showing an alternative arrangement for attaching the shroud to the frame;

FIG. **25** is a front perspective view of a mask system according to another embodiment of the present invention;

FIG. **26** is a rear perspective view of the mask system of FIG. **25**;

FIG. **27** is a front perspective view of a mask system according to another embodiment of the present invention;

FIG. **28** is an exploded view of the mask system shown in FIG. **27**;

FIG. **29** is an enlarged front perspective view of the mask system shown in FIG. **17**;

FIG. **30** is a side view of the mask system shown in FIG. **27**;

FIGS. **31-1** is a rear view of a cushion according to an embodiment of the present invention;

FIG. **31-2** is a front view of the cushion shown in FIG. **31-1** with a partial cut-away;

FIG. **31-3** is a cross-section view through line **31-3**-**31-3** in FIG. **31-1**;

FIG. **31-4** is a cross-section view through line **31-4**-**31-4** in FIG. **31-1**;

FIG. **31-5** is a cross-section view through line **31-5**-**31-5** in FIG. **31-1**;

FIGS. **32-1** to **32-3** illustrate top, front, and side views respectively of a concertina section according to an embodiment of the present invention;

FIG. **33** is a side view of a mask system according to a variation of the present invention;

FIG. **34** illustrates a cushion including a concertina section according to an embodiment of the present invention;

FIGS. **35-1** to **35-3** are front, side, and rear views of a mask system according to another embodiment of the present invention;

FIG. **36** is a perspective view of a shroud for a mask system according to an embodiment of the present invention;

FIGS. **37-1** to **37-3** are perspective, front, and side views of a mask system according to another embodiment of the present invention;

FIGS. **38-1** to **38-5** are perspective, front, top, side, and bottom views of a shroud of the mask system shown in FIGS. **37-1** to **37-3**;

FIGS. **39-1** to **39-6** are perspective, front, side, bottom, and top views of a mask system according to another embodiment of the present invention;

FIGS. **40-1** and **40-2** are perspective and side views of a mask system according to another embodiment of the present invention;

FIG. **40-3** is a perspective view of the frame of the mask system shown in FIGS. **40-1** and **40-2**;

FIGS. **40-4** and **40-5** illustrate a retaining member of the frame shown in FIG. **40-3**;

FIGS. **40-6** and **40-7** illustrate a clip-on upper headgear connector of the mask system shown in FIGS. **40-1** and **40-2**;

FIGS. **41-1** and **41-2** are rear and front perspective views of a mask system according to another embodiment of the present invention;

FIGS. **41-3** and **41-4** are exploded views of the mask system shown in FIGS. **41-1** and **41-2**;

FIGS. **41-5** to **41-12** are various views of a clip-on upper headgear connector of the mask system shown in FIGS. **41-1** and **41-2**;

FIG. **42-1** is a rear perspective view of a mask system according to another embodiment of the present invention;

FIG. **42-2** is an exploded view of the mask system shown in FIG. **42-1**;

FIGS. **42-3** to **42-7** are various views of a clip-on upper headgear connector of the mask system shown in FIG. **42-1**;

FIGS. **43-1** to **43-4** are perspective, side, front, and rear views of a mask system according to another embodiment of the present invention;

FIG. **44** illustrates a mask system according to another embodiment of the present invention; and

FIG. **45** illustrates a mask system according to another embodiment of the present invention.

DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

The following description is provided in relation to several embodiments or examples which may share common characteristics and features. It is to be understood that one or more features of any one embodiment or example may be combinable with one or more features of the other embodiments or examples. In addition, any single feature or combination of features in any of the embodiments or examples may constitute additional embodiments or examples.

In this specification, the word "comprising" is to be understood in its "open" sense, that is, in the sense of "including", and thus not limited to its "closed" sense, that is the sense of "consisting only of". A corresponding meaning is to be attributed to the corresponding words "comprise", "comprised" and "comprises" where they appear.

The term "air" will be taken to include breathable gases, for example air with supplemental oxygen.

The term "shroud" will be taken to include components that partially or fully cover a second component within the illustrated embodiments. In an embodiment, the shroud may include the component that partially covers or is mounted on the frame components of the illustrated embodiments.

The term "positive connection" will be taken to include connections between components of the illustrated embodiments wherein connectors mounted on respective components are adapted to engage each other respectively.

1. Mask System

Embodiments of the invention are directed towards a mask system provided without a forehead support adapted to engage the patient's forehead. Such arrangement provides the mask system with a less obtrusive arrangement which does not significantly affect the patient's field of view. Although the system is designed such that a forehead support is not required, such a forehead support can be added if desired.

As described in greater detail below, the mask system includes a frame, a cushion provided to the frame and adapted to form a seal with the patient's face, a shroud provided to the frame and adapted to attach headgear, and an elbow provided to the frame and adapted to be connected to an air delivery tube that delivers breathable gas to the patient. Headgear may be removably attached to the shroud to maintain the mask system in a desired adjusted position on the patient's face. The mask system is intended for use in positive pressure therapy for users with Obstructive Sleep Apnea (OSA) or another respiratory disorder.

While each embodiment below is described as including a full-face or oro-nasal interface type, each embodiment may be adapted for use with other suitable interface types. That is, the interface type is merely exemplary, and each embodiment may be adapted to include other interface types, e.g., nasal interface, nasal mask, nasal prongs, etc.

2. Stabilizing Mechanisms

The stabilizing mechanisms (e.g., frame, shroud, headgear with associated headgear vectors) of a mask system according to embodiments of the invention are structured to accommodate the elimination of a forehead support from a full-face type interface. For example, a forehead support typically eliminates rotation of the mask system in the sagittal and coronal planes, so the mask system and headgear according to embodiments of the invention are structured to take on these functions since there is no forehead support.

The headgear is connected to the top and bottom of the frame either directly or via the shroud, which shroud provides headgear connection points for headgear positioned and arranged to stably maintain the mask system in position on the patient's face.

2.1 Frame

As shown in FIGS. **1**, **1**B-**1**E, and **2-5**, the frame **1040** of the mask system **1010** is structured to maintain the cushion **1060**, shroud **1020**, and elbow **1070** in an operative position with respect to the patient's face. The frame **1040** is constructed (e.g., injection molded) from a more rigid material (e.g., polyurethane) than the cushion **1060** (made of, e.g., silicone), however other materials may function likely as well (e.g., polycarbonate). In an embodiment, the frame has a general wall thickness of about 1-2 mm, e.g., 1.5 mm.

The frame **1040** defines a breathing chamber or cavity adapted to receive the patient's nose and mouth and provide air communication to the patient. One or the lower portion of the frame **1040** includes an opening **1046** adapted to receive or otherwise communicate with the elbow **1070** (e.g., swivel elbow) and another or upper portion of the frame **1040** includes a vent arrangement **1076** for gas washout. In addition, the upper portion of the frame **1040** includes an inter-

facing structure **1048** adapted to interface or otherwise removably connect to the shroud **1020**.

FIGS. **27-30** shows a mask system **10** including a frame **40** with a cushion **44** that provides a sealing portion or sealing ring adapted to form a seal with the patient's nose and/or mouth. Also, the frame **40** includes an opening **46** that is adapted to communicate with the elbow **70**.

2.2 Shroud

As shown in FIGS. **1** and **3-6**, the shroud **1020** is connected to the frame **1040** and is structured to attach headgear to the mask system. In an embodiment, the shroud **1020** is constructed (e.g., injection molded) of a resilient material including but not limited to plastic or nylon (e.g., Nylon 12). However, the shroud may be constructed of other suitable materials, e.g., polycarbonate, polypropylene, thermoplastic elastomer (TPE), Pocan®, etc. In an embodiment, the shroud has a general wall thickness of about 1-2 mm, e.g., 1.3 mm.

The top end of the shroud **1020** is adapted to be positioned proximal to the nasal bridge region or nose of the patient and the bottom end is adapted to be positioned proximal to the mouth or chin of the patient. The top end includes an opening or vent receiving hole **1021** to accommodate the vent arrangement **1076** that protrudes from the frame **1040**, and the bottom end includes an opening or elbow hole **1032** to accommodate the elbow **1070** and elbow opening into the frame **1040** (e.g., shroud provides no contact with elbow when assembled).

Upper headgear connectors **1024** extend from each side of the top end, and lower headgear connectors **1025** extend from each side of the lower end. The headgear connectors **1024**, **1025** may be integrally molded or otherwise attached to the shroud.

2.2.1 Upper Headgear Connectors

Each upper headgear connector **1024** includes an elongated arm **1026** and a slot or receiving hole **1027** at the free end of the arm **1026** adapted to receive a respective headgear strap. In use, the arms **1026** extend around the face of the patient in a generally concave angle below the eyes of the patient so as to avoid the patient's field of view, i.e., direct headgear away from the patient's eyes. For example, as shown in FIG. **1**E, each arm **1026** may extend at an angle α between about 10-25° (e.g., 17°) with respect to horizontal. That is, each arm **1026** is suitably formed, shaped, or contoured to follow the contours of the patient's face and avoid line of sight in use. In an embodiment, the shape of the arms may be generally arcuate and adapted to extend in a direction across the cheek of the patient, while avoiding the eyes or limiting the field of vision. In an embodiment, the arms may be integrally molded to the shroud of the mask system. One possible advantage of molding the arms onto the shroud is that it greatly increases manufacturability and also the shroud may be easily replaced in the case of accidental breakage of the arms rather than replacing the complete mask system. Additionally, molding of the arms onto the shroud may greatly increase the strength of the connection and reduce or limit the actual likelihood of breakage of the arms.

In an embodiment, the arms **1026** are at least semi-rigid (e.g., relatively rigid) so as to prevent up and down movement or bending of the arms relative to the face of the patient. Thus, the arms **1026** may act as rigidizers to effectively act as a level arrangement and generate a mechanical advantage wherein the pressure or force applied to top end of the mask system is readjusted to a fulcrum point being about the center of balance between the top and bottom ends of the mask system. In an embodiment, the arms are attached to the highest possible point relative to the mask system to additionally stabilize the configuration. In an embodiment, the fulcrum point or moment of pivoting is positioned between the upper and lower connection points of the straps, and wherein the design, angle, length and/or configuration of the arms **1026** may effectively adjust the fulcrum point. In the illustrated embodiment, the fulcrum point is shown to be between the vent arrangement and elbow of the mask system. Additionally, when positioned on the face, the mask system may have a fulcrum point around or about the region between the bottom of the patient's nose and lip area. This feature effectively stabilizes the mask system on the patient's face without the traditional need for a forehead support.

The net result of the arms **1026** mounted in a position extending from the top end of the mask system around the face of the patient is that the mask system is more stable and reduces the net torsional forces experiences about the x-axis **1001** (see FIG. **1**) for the mask system in use. Please note that the arms **1026** may be rigidly connected to the mask system in other suitable positions to generate a similar result.

In an embodiment, the arms **1026** may be used to stabilize the mask system by contacting the patient's face at the cheeks. A cheek pad may be provided to the inner surface of the arm to support the arm on the patient's cheek in use. Also, the arms **1026** may be enveloped in a soft fabric sleeve to act as additional padding against the cheeks of the patient. The soft fabric sleeve may be in the configuration of an elastic tube covering a portion of the arms **1026**.

2.2.2 Lower Headgear Connectors

Each lower headgear connector **1025** includes an abbreviated arm and a clip receptacle **1031** at the free end of the arm adapted to be removably interlocked with a headgear clip associated with a respective headgear strap. The clips allow for easier positioning or donning/removal of the mask system. In an embodiment, the abbreviated arms and clips are also relatively rigid so as to prevent lateral movement of the arms along the y-axis **1002**, relative to the mask system in use.

FIGS. **27-30** illustrate an exemplary headgear clip **33** adapted to be removably interlocked with a clip receptacle **31**. As best shown in FIG. **28**, each clip **33** includes two spring arms **35** adapted to interlock with the respective clip receptacle **31** with a snap-fit and a slot **37** adapted to receive a respective headgear strap in use.

2.2.3 Alternative Headgear Connectors

As shown in FIGS. **27-30**, the arm **26** may be removably coupled to the shroud, e.g., arm **26** includes clip structure adapted to removably interlock with a clip receptacle provided to the shroud. This arrangement allows different styles of upper and lower headgear connectors to be used with the shroud, e.g., arms for both upper and lower headgear connectors, clips for both upper and lower headgear connectors, different length arms for upper and lower headgear connectors, etc.

However, the shroud may provide other suitable arrangements for attaching headgear straps of headgear. Also, the shroud may include one or more additional components, e.g., forehead support.

2.2.4 Headgear Connector Positioning

In the embodiment of FIGS. **1-6**, the upper and lower headgear connectors **1024**, **1025** provide headgear connection points that are as far from each other as possible (i.e., top and bottom of frame) to allow for greater adjustability (e.g., allows adjustment at the top and bottom of the mask system) and stability (e.g., anchor points spread out around the mask system so more secure on the patient's face). Also, the upper headgear connectors are positioned as close to the top of the mask system as possible without obstructing the patient's eyes in use.

2.2.5 Separate Shroud

In the embodiment of FIGS. **1-6**, the shroud **1020** is formed separately (e.g., molded) and attached to the frame **1040**. Such arrangement facilitates molding of the shroud, allows different materials to be used for the frame and shroud (e.g., frame can be semi-rigid or rigid for stability and shroud with headgear rigidizers can be flexible for adjustment, allows the shroud to hide elbow retention features around elbow/frame opening for retaining elbow to frame (e.g., provides visual shroud for aesthetics), allows frame to be free of lower clip receptacles, allows shroud to be used with different size frames, and allows the shroud to be designed or stylized to minimize obtrusiveness of the mask system. The separate shroud may also allow the headgear, frame, cushion, and/or elbow to be replaced or washed independently.

2.2.6 Sleeves

In an embodiment, soft fabric sleeves may be mounted on the upper and/or lower headgear connectors. For example, the sleeves may be elastic and adapted to slide over the arms of the headgear connectors to form a tight fit. In an embodiment, the sleeves form elastic tubes. The sleeves may be padded to increase the comfort of the mask system in use. The sleeves may be particularly useful where the arms of the headgear connectors contact the patient's skin, e.g., to protect the patient's skin from irritation.

2.2.7 Arm Extends Over the Patient's Ear

FIGS. **35-1** to **35-3** and **36** illustrate a shroud **220** for mask system **210** according to another embodiment of the present invention. The shroud **220** includes an annular retaining portion **222** structured to retain the frame **240** and upper and lower headgear connectors **224**, **225** on each side of the retaining portion **222**. In the illustrated embodiment, the shroud **220** is integrally formed in one piece (e.g., see FIG. **36**).

In the illustrated embodiment, each upper headgear connector **224** includes an elongated arm **226** and a slot **227** at the free end of the arm **226** adapted to receive a respective rear strap **298** in use. As illustrated, the arm **226** is suitably contoured to extend along the cheeks and over the patient's ear just anterior of the patient's temple and retain the respective rear strap **298** in spaced relation over the patient's ear, e.g., to avoid the strap rubbing or irritating the patient's ear in use.

Also, each arm **226** is structured to extend along and engage an upper strap **292** of the headgear in use. As illustrated, each arm **226** is secured to the upper strap **292** to add rigidity to the strap and stabilize the mask system on the patient's face in use. In addition, the strap **292** provides padding to the arm **226** on the patient's face in use. In an embodiment, the upper strap **292** may be fixed to the arm **226** by gluing or stitching for example. Alternatively, the arms **226** may be encapsulated by or inserted into respective straps **292** so that the arms **226** are substantially not visible.

Each lower headgear connector **225** includes an abbreviated arm **228** with a slot **229** at the free end of the arm **229** adapted to receive a respective lower strap **294** in use. As illustrated, the arm **228** is suitably oriented to retain the respective lower strap **294** in spaced relation under the patient's ear, e.g., to avoid the strap rubbing or irritating the patient's ear in use.

In an embodiment, each arm may be attached to the upper end of the mask system and curves below the patient's field of vision or eyes and curves upwards at an angle between about 10 to 20 degrees away from the horizontal axis.

In an alternative embodiment, as shown in FIG. **36**, each lower headgear connector **225** may include a clip receptacle **231** adapted to be removably interlocked with a headgear clip (not shown) associated with a respective lower strap **294**. In an embodiment, the headgear clip receptacle and clip may be similar to that on ResMed's Mirage Liberty™ mask. Exemplary clip arrangements are disclosed in U.S. Patent Publication Nos. 2007/0144525 and 2006/0283461, each of which is incorporated herein by reference in its entirety.

2.2.8 Shroud without Upper Headgear Connector

FIGS. **37-1** to **37-3** illustrate a mask system **310** according to another embodiment of the present invention. As illustrated, the mask system **310** includes a shroud **320**, a frame **340**, a cushion **344**, and an elbow **370**.

As best shown in FIGS. **38-1** to **38-5**, the shroud **320** includes an opening **322** structured to receive the elbow **370** and a headgear connector **325** on each side thereof. In the illustrated embodiment, each headgear connector **325** includes a clip receptacle **331** adapted to be removably interlocked with a headgear clip (not shown) associated with a respective lower headgear strap.

The frame **340** is removably attached to the shroud **320**, e.g., fingers and tabs **345** extending from opening **322** adapted to engage collar of frame **340**.

The frame **340** includes an upper headgear connector **324** on each upper side thereof. Each headgear connector **324** includes a clip retainer **333** adapted to be removably interlocked with a headgear clip (not shown) associated with a respective upper headgear strap.

FIGS. **39-1** to **39-6** illustrate an alternative version of the mask system **310**, which is indicated with similar reference numerals. As illustrated, the frame **340** is provided without upper headgear connectors, and the each clip receptacle **331** includes an alternative configuration (e.g., holes for snap-fit tabs on the clip). Also, the shroud **320** in FIGS. **39-1** to **39-6** includes support bars **329** structured to wrap around respective auxiliary ports **343**, while the shroud **320** in FIGS. **37-1** to **38-5** includes support bars **329** that extend in front of respective auxiliary ports **343**.

2.3 Headgear

Headgear may be removably attached to the headgear connectors **1024**, **1025** of the shroud **1020** to maintain the mask system **1010** in a desired position on the patient's face, e.g., see FIG. **1**B.

As shown in FIG. **9**, the headgear **1090** includes a pair of upper and lower straps **1092**, **1094** with the upper straps **1092** removably attached to respective upper headgear connectors **1024** and the lower straps **1094** removably attached to respective lower headgear connectors **1025**. The free end of each strap may include a Velcro® tab structured to engage the remainder of the strap to secure the strap in place. Such Velcro® attachment also allows adjustment of the length of the straps. However, the upper and lower headgear straps may be secured to the shroud in any other suitable manners, e.g., adjustable ladder-lock arrangement, etc.

The upper straps **1092** split at the crown of the patient's head to top straps **1096** (e.g., connected to one another by a buckle) adapted to pass over the top of the patient's head in use and rear straps **1098** adapted to pass behind the patient's head in use. In an embodiment, the headgear **1090** is structured to be self-supporting.

In FIG. **9**, the top straps **1096** are adapted to be connected to one another by a buckle. In an alternative embodiment, as shown in FIG. **27-30**, headgear **90** may include upper and lower straps **92**, **94**, top strap **96**, and rear strap **98**, with the top straps **96** integral with one another.

The upper straps **1092** are designed to adjust the position of the mask in a similar way that an adjustable forehead support would alter the position of the mask system, i.e., move the top of the mask system closer or further away from the patient's nasal bridge.

Without the forehead support, the headgear is connected at the top and bottom of the mask frame **1040** via the shroud **1020**, and in order to avoid the eyes and ears, the arm **1026** of the upper headgear connector extends at an angle. In doing so, the headgear vectors V**1** and V**2** (see FIGS. **1** and **1**B) are aligned such that the mask system may have a tendency to ride up the patient's face (i.e., upper headgear connectors position upper headgear vectors upwardly from horizontal and lower headgear connectors position lower headgear vectors generally horizontal). By splitting the upper headgear strap **1092** at the crown of the patient's head (i.e., top and rear straps **1096**, **1098**), the upper headgear vectors are realigned to prevent the mask system from sliding up the patient's face.

2.3.1 Headgear Adjustment

FIGS. **35-1** to **35-3** illustrate headgear **290** attached to the headgear connectors **224**, **225** of the shroud **220** to maintain the mask system in a desired position on the patient's face.

In the illustrated embodiment, the headgear **290** includes a pair of upper or top straps **292**, a pair of lower or bottom straps **294**, and a pair of rear straps **298**. In use, the upper straps **292** are secured to respective upper connectors or arms **226**, the lower straps **294** are removably attached to respective lower connectors via slots **229**/clip arrangement **231**, and the rear straps **298** are removably attached to respective upper connectors via slots **227**. The upper straps **292** may include upper strap portions adapted to pass over the top of the patient's head and couple to one another, e.g., via a headgear buckle or adjustable ladder-lock arrangement **299**. In the illustrated embodiment, the lower straps **294** and rear straps **298** are formed in one piece.

This headgear arrangement allows adjustment to occur at three positions, i.e., upper straps **292** at the headgear buckle **299**, lower straps **294** at the slot **229**/clip **231** connection, and rear straps **298** at the slot **227** connection.

As illustrated, the free end of each strap may include a hook and loop tab **295** (e.g., Velcro®) structured to engage the remainder of the strap to removably secure the strap in place. Such hook and loop attachment also facilitates adjustment of the length of the straps.

In the illustrated embodiment, the lower straps **294** and rear straps **298** are adapted to join and pass behind the patient's head in use (e.g., see FIG. **35-3**). As illustrated, the lower straps **294** join at an angle α (e.g., similar to the bottom strap in ResMed's Mirage Liberty mask) to prevent the strap from irritating the patient's neck and/or prevent movement of the strap due to movement of the patient's neck in use.

In an embodiment, the headgear may be similar to that for ResMed's Mirage Liberty mask, however the top straps have been modified and there is an added rigidizer system. The top straps may be similar to ResMed's Swift style headgear, with the rigidizers extending along the sides.

2.3.2 Alternative Headgear Material

FIGS. **43-1** to **43-4** illustrate a mask system **610** including a mask **615** and headgear **690** according to another embodiment of the present invention. In the illustrated embodiment, the headgear **690** includes an arrangement of straps wherein some of the straps are constructed of silicone and some of the straps are constructed of Breath-O-Prene™ material. However, the headgear may be constructed such that the straps are completely constructed of silicone or completely constructed of Breath-O-Prene™.

As illustrated, the lower strap portion **692** of the headgear is constructed of Breath-O-Prene™ and extends along the cheeks and around the back of the patient's head. The upper strap portion **694** of the headgear is constructed of silicone and includes side straps **694**(**1**) that extend along the upper cheek and over the patient's ear, a top strap **694**(**2**) that extends over the top of the patient's head, rear straps **694**(**3**) that extend behind the patient's head and connects to the lower strap portion **692** (see FIG. **43-4**), and connecting portions **694**(**4**) that extend from respective side straps **694**(**1**) in front of the patient's ear and connect to the lower strap portion **692**.

The headgear straps may be connected to the mask in any suitable manner. For example, in the illustrated embodiment, the lower strap portion **692** is connected to the mask by a headgear clip arrangement and the upper strap portion **694** is connected to the mask using an elongated buckle **695** with buckle portions on each end thereof.

In an embodiment, the headgear straps are arranged such that the force vectors applied by the headgear to the mask are substantially perpendicular to the mask and substantially parallel to one another (e.g., as shown by the arrows in FIG. **43-2**). This arrangement enhances the mask seal as the headgear forces the mask directly into the patient's face.

3. Seal

The seal (i.e., cushion) of the mask system is structured to accommodate the elimination of a forehead support from a full-face type interface.

3.1 Cushion

As shown in FIGS. **1-5** and **7-8**, the cushion **1060** is structured to interface with the frame **1040** and form a seal with the patient's nose and mouth in use. In the illustrated embodiment, the cushion is a full-face cushion adapted to engage the patient's face generally along nasal bridge, cheek, and lower lip/chin regions of the patient's face. However, other cushion interfaces are possible, e.g., nasal.

The cushion **1060** is structured be more compliant or flexible (e.g., particularly in the nasal bridge region) to accommodate more movement due to loss of some stability without a forehead support.

The cushion **1060** is constructed of a soft and flexible biocompatible material, e.g., such as silicone. In the illustrated embodiment, the cushion **1060** includes a dual wall configuration wherein the cushion comprises an undercushion or support wall **1062** underneath a membrane **1064** as shown in FIG. **8**.

The membrane **1064** is generally softer and less stiff than the undercushion **1062** and provides a seal against the patient's face in use. The membrane may be relatively thin to allow for wider fit range and better conformance to the patient's face in view of less mask stability with a forehead support. The undercushion is structured to generally support the membrane and prevents collapse of the membrane when the mask system is attached and tightened using the headgear.

The membrane **1064** is generally concave and curves inwards towards the breathing chamber. The undercushion **1062** may also curve inwardly but is generally shorter, thicker, and more rigid than the membrane.

In an embodiment, the undercushion **1062** at the regions of the nasal bridge and/or chin of the patient is shorter in height or completely absent and the height from the tip to base of the undercushion **1062** may be between about 0 mm and 30 mm. The membrane is generally longer than the undercushion **1062** at any given cross-section and may be between about 1 mm and 40 mm. For example, FIG. **8**B illustrates a cross-section through nasal bridge and chin regions of the cushion to illustrate the membrane **1064** without an undercushion in these regions.

In an embodiment, the undercushion **1062** may only be provided in selected regions of the mask system, e.g., where the mask system is to be pushed away from the patient's face. Certain pre-determined regions of the patient's face may be preferably avoided for applying pressure by the tightening of

the headgear. In the illustrated embodiment, the nasal bridge and chin regions of the patient do not include an undercushion **1062**. In these regions, the undercushion is only provided along lateral sides of the cushion (e.g., see FIG. **7**) which press against the cheeks of a patient so as to more evenly distribute the force vectors applied by the mask system in use. In an embodiment, the undercushion may be relatively stiff along the cheek regions because these points of contact are acting as anchor points, i.e., holds mask system in position to provide effective seal.

This configuration of avoiding the nasal bridge and chin of the patient may increase the comfort of the mask system for patients by reducing the pressure or force applied to sensitive areas or to protruding regions of the patient's face that experience relatively higher contact pressures. Additionally, this arrangement avoids the cushion pinching the nasal bridge of the patient when the mask system is adjusted. Additionally, the cushion of this embodiment may be noticeably softer in the regions of the nasal bridge and chin because of the absence of the undercushion.

In an embodiment, the undercushion may include a variable height, stiffness, and/or thickness to generate a variable softness in the aforementioned predetermined regions of the face that require lighter support.

In the illustrated embodiment, the cushion may be structured to seal lower down on the patient's nasal bridge and the eye sockets so that the cushion is less obtrusive.

In an embodiment, the cushion may be generally frosted except at patient contacting surfaces where it is polished. In an embodiment, the frosting of the cushion may reduce restriction between the face and membrane and/or the membrane and undercushion. The frosting allows the surface of the membrane and undercushion to slide against each other's respective surface without the same restriction of unfrosted silicone. This feature may also prevent or limit sticking of the membrane to the undercushion components and also may generally improve the overall comfort and sealing properties of the cushion. Additionally, the frosting of the cushion may be easier to manufacture and may lead to a reduction of costs of manufacturing. The cushion may be constructed of frosted silicone or other suitable materials.

3.2 Cushion Lower on Nasal Bridge

FIGS. **31-1** to **31-5** illustrate various views of a cushion **44** (e.g., constructed of silicone) according to an embodiment of the present invention. As illustrated, the cushion **44** includes a base wall **44(1)** provided to the frame, an undercushion layer (UCL) **44(2)** extending away from the base wall **44(1)**, and a membrane **44(3)** provided to substantially cover the UCL **44(2)** and provide a sealing structure. In the illustrated embodiment, the cushion **44** is structured to sit lower on the nasal bridge to reduce mask obtrusiveness and improve "line of sight" in use.

Also, as best shown in FIGS. **31-3** and **31-5**, the UCL **44(2)** design in the nasal bridge region is structured to provide improved stability across the nasal bridge in use. As shown in FIGS. **31-1** and **31-3**, the UCL is not provided in the lower lip/chin region. However, other arrangements of the UCL are possible, e.g., UCL around entire perimeter.

In an embodiment of the cushion shown in FIGS. **31-1** to **31-5**, D**1** may be about 15-20 mm, e.g., 18.2 mm, D**2** may be about 53-59 mm, e.g., 55.8 mm, D**3** may be about 88-93 mm, e.g., 90 mm, D**4** may be about 78-83 mm, e.g., 81.1, D**5** may be about 58-63 mm, e.g., 60 mm, D**6** may be about 95-100 mm, e.g., 98.1 mm, D**7** may be about 57-62 mm, e.g., 59.7 mm, D**8** may be about 77-82 mm, e.g., 79 mm, D**9** may be about 88-93 mm, e.g., 90.7 mm, D**10** may be about 30-35 mm, e.g., 33.1 mm, D**11** may be about 14-19 mm, e.g., 16.4 mm, D**12** may be about 8-13 mm, e.g., 9.6 mm, D**13** may be about 0.3-0.5 mm, e.g., 0.35 mm, D**14** may be about 0.4-0.6 mm, e.g., 0.5 mm, and D**15** may be about 0.3-0.5 mm, e.g., 0.4 mm. Although specific dimensions and ranges are indicated, it is to be understood that these dimensions and ranges are merely exemplary and other dimensions and ranges are possible depending on application. For example, the exemplary dimensions may vary by 10-20% or more or less depending on application.

3.3 Cushion Higher on Nasal Bridge

FIGS. **35-1** and **35-2** illustrate a full-face cushion **244** adapted to engage the patient's face generally along nasal bridge, cheek, and lower lip/chin regions of the patient's face. In this embodiment, the cushion **244** is structured such that it is positioned higher on the bridge of the nose for sealing and comfort (e.g., with respect to the cushion **44** described above). The cushion **244** may also be better for anthropometrics, i.e., the cushion will fit more people.

In an embodiment, the cushion **244** may include a concertina section as described below (e.g., in the nasal bridge region) to enhance the flexibility of the cushion in use.

3.4 Concertina Section

As best shown in FIGS. **30** and **33**, a concertina section **50** may be provided in a nasal bridge region of the cushion and/or frame. As illustrated, the concertina section **50** includes a bellows structure with one or more folds **52** that provide a higher degree of flexibility or increased movement. That is, the concertina section **50** provides a higher level of adaptability or flexibility to the nasal bridge region of the cushion/frame which is a more sensitive region of the patient's face in use. Moreover, the concertina section **50** provides increased movement without compromising seal.

FIGS. **32-1** to **32-3** illustrate various views of a concertina section **50** (isolated from the remainder of the cushion/frame) with one or more folds **52** according to an embodiment of the present invention. As best shown in FIG. **32-3**, the folds may have different lengths, depths, and/or contours with respect to one another to optimize the concertina effect, e.g., provide sufficient degree of movement without compromising seal. For example, as shown in FIG. **32-3**, each fold **52** includes a first side wall **52(1)** and a second side wall **52(2)** that interconnects adjacent side walls **52(1)**.

In the illustrated embodiment, the first side walls **52(1)** and/or the second side walls **52(2)** may become progressively longer away from the patient's face. For example, the first side wall **52(1)** and/or the second side wall **52(2)** adjacent patient's face, or the combination of side walls **52(1)** and **52(2)**, may have a length that is longer than and in some cases significantly longer than the adjacent side wall **52(1)** and/or **52(2)** (e.g., one side wall at least 25% greater than and up to 5× as long as the other side wall, e.g., 1×, 2×, 3×, or 4×).

The folds may be constructed and arranged to provide a predetermined order of movement or folding, e.g., folds structured to fold in a sequential or progressive manner wherein one fold collapses before an adjacent fold collapses. For example, upon application of force, the folds closest to the patient's face may fold or collapse before the folds furthest from the patient's face. Also, the folds may be constructed and arranged to provide various degrees of fold or collapse, e.g., folds may fold or collapse more than others.

In an embodiment of the concertina section shown in FIGS. **32-1** to **32-3**, D**1** may be about 50-60 mm, e.g., 55.7 mm, D**2** may be about 5-15 mm, e.g., 9.7 mm, and D**3** may be about 0.3-0.5 mm, e.g., 0.4 mm. Although specific dimensions and ranges are indicated, it is to be understood that these dimensions and ranges are merely exemplary and other dimensions and ranges are possible depending on application. For

example, the exemplary dimensions may vary by 10-20% or more or less depending on application.

It should be appreciated that a concertina section **50** may be provided in other regions of the cushion and/or frame, e.g., depending on patient comfort. For example, the concertina section **50** may be provided around the entire perimeter of the cushion and/or frame or may be provided in selected regions of the cushion and/or frame.

Also, the flexibility of the concertina section **50** may be varied and may be varied in different regions of the cushion and/or frame, e.g., depending on patient comfort. For example, the cushion and/or frame may include a concertina section in the nasal bridge region with a relatively high degree of flexibility and a concertina section in the lower lip/chin region with a relatively low degree of flexibility. The flexibility of the concertina section **50** may be varied by varying the number of folds **52** (e.g., 1-5 folds), the wall lengths, the wall thickness of the folds **52**, the depth of the folds **52**, etc.

As noted above, the cushion and frame may be co-molded of two parts with different materials/rigidities or may be integrally formed of the same material. In both embodiments, the concertina section may be provided in the frame and/or the cushion.

In FIGS. **27-30**, the cushion **44** and frame **40** are co-molded of two parts with the concertina section **50** provided in the frame **40**. The frame **40** and cushion **44** include different rigidities in order to optimize the function of each part. For example, one part (i.e., cushion **44**) may be constructed of a relatively soft, supple material to optimize the sealing effect and the other part (i.e., frame **40**) may be constructed of a more rigid material to provide adequate support for the cushion while at the same time allowing a sufficient degree of movement to optimize the concertina effect. While the frame is more rigid than the cushion, the frame may be constructed of a flexible material to allow the concertina effect.

In FIG. **33**, the frame **40** and cushion **44** are integrally formed in one piece with the concertina section **50** provided in the frame **40**. The material properties and/or dimensions may be selectively modified to optimize sealing and concertina effects.

For both embodiments of FIGS. **27-30** and **33**, it should be appreciated that the concertina section may be alternatively provided in the cushion **44** or in both the frame **40** and cushion **44**. For example, FIG. **34** illustrates a concertina section **50** integrally formed with the cushion **44** in the nasal bridge region.

4. Elbow

As shown in FIG. **3**, the elbow **1070** (e.g., constructed of a relatively hard material such as polycarbonate or polypropylene) includes a first end portion **1074**(**1**) and a second end portion **1074**(**2**). The first end portion **1074**(**1**) provides an interfacing structure structured to interface or otherwise attach to the frame **1040**. The second end portion **1074**(**2**) is adapted to be connected to an air delivery tube.

4.1 Elbow Connection to Frame/Shroud

As shown in FIGs. **27-30**, the shroud module **20** is structured to maintain the elbow module **70** in an operative position with respect to the patient's face. That is, the shroud module **20** acts as a carrier and bearing surface for the elbow module **70**. The shroud module **20** and elbow module **70** may connect with a friction fit, snap-fit, mechanical interlock, or other suitable attachment mechanism. However, other suitable arrangements for attaching the elbow module to the frame module are possible.

In FIGs. **27-30**, the elbow module **70** may be rotatably attached to the shroud module **20** so that the elbow module **70** may be rotated relative to the shroud module **20** in use, e.g., 360° rotation.

The frame **1040** is structured to maintain the elbow **1070** in an operative position with respect to the patient's face. That is, the frame acts as a carrier and bearing surface for the elbow. The frame and elbow may connect with a friction fit, snap-fit, mechanical interlock, or other suitable attachment mechanism. However, other suitable arrangements for attaching the elbow to the frame are possible.

In the illustrated embodiment, the elbow **1070** includes a series of tangs **1075** adapted to releasably engage within the opening **1046** of the frame **1040**, e.g., with a snap-fit. The tangs **1075** hold the elbow in place (e.g., preferably a relatively airtight connection) and permit rotation or swiveling of the elbow with respect to the frame.

That is, the elbow is rotatably attached to the frame so that the elbow may be rotated relative to the frame in use, e.g., 360° rotation. This arrangement allows the elbow to assume different orientations in use, e.g., depending on patient preference. For example, the elbow may assume a first orientation so that the elbow extends generally downwardly from the mask to direct the air delivery tube under the patient's head in use. Alternatively, the elbow may be rotated and assume a second orientation so that the elbow extends upwardly from the mask to direct the air delivery tube over the patient's head in use. In an embodiment, the frame and elbow may be constructed of dissimilar materials to prevent or at least reduce squeak between the components in use.

The second end portion of the elbow may be provided to a swivel joint adapted to be connected to the air delivery tube. For example, FIGS. **27-30** illustrate a swivel joint **80** provided to the second end portion **74**(**2**) of elbow **70**. In the illustrated embodiment, the swivel joint **80** is provided to a short tube **82** (e.g., extendable and retractable tube) that interconnects the elbow with the air delivery tube. In an embodiment, the swivel joint **80** may be integrally formed in one piece with the short tube **82**.

4.2 AAV

The elbow **1070** includes a slot **1081** to receive an anti-asphyxia valve (AAV), a port **1079** that is selectively closed by a flap portion of the AAV (depending on the presence of pressurized gas), and structure for attaching the AAV, e.g., with a snap-fit.

FIGS. **27-30** illustrate an exemplary AAV **85** including a flap portion **86** to selectively close port **79** in elbow **70**. In this embodiment, a clip portion **88** is provided to the flap portion **86** for attaching the AAV **85** to the elbow **70**. In the illustrated embodiment, the flap portion **86** and the clip portion **88** are co-molded with one another to form a one-piece, integrated component. However, the flap portion **86** and clip portion **88** may be secured to one another in other suitable manners, e.g., mechanical interlock.

In an embodiment, the flap portion **86** may be constructed of a relatively soft elastomeric material (e.g., silicone) and the clip portion **88** may be constructed of a more rigid material (e.g., rigid plastic) for interfacing with the elbow **70**.

The clip portion **88** of the AAV **85** includes structure for removably interlocking with the elbow **70**, e.g., with a snap-fit. For example, the clip portion **88** may include tabs structured to interlock with respective recesses/protrusions provided to the elbow.

FIGS. **35-1** and **35-2** illustrate an elbow **270** including a port **279** that is selectively closed by a flap portion **286** of the AAV **285** (depending on the presence of pressurized gas).

Also, FIGS. **37-1** to **37-3** illustrate elbow **370** including a port **379** and a slot **381** to retain the AAV.

Alternative embodiments of the AAV are disclosed in PCT Application No. PCT/AU2006/000031, which is incorporated herein by reference in its entirety.

4.3 Large Diameter End Portion

As shown in FIGS. **27-30**, the first end portion **74**(**1**) of the elbow **70** may provide a relatively large diameter which allows the potential for cleaner/smoother lines thereby contributing to the overall mask aesthetic and reduced obtrusiveness. In addition, the relatively large diameter elbow offers the potential for the patient's nose to protrude into the elbow cavity thereby permitting the mask to be brought closer to the patient's face (i.e., reduced obtrusiveness), less moment since center of gravity of mask is closer to the patient's face, and/or improved line of sight.

5. Modular Design

The mask system provides a modular design that allows different styles and/or sizes of the frame (also referred to as a frame module), shroud (also referred to as a shroud module), cushion (also referred to as a cushion module), and/or elbow (also referred to as an elbow module) to be interchanged or mixed and matched with one another to provide a more customized mask system for the patient. In addition, such design allows selected modules to be easily replaced, e.g., treatment requirements change, worn out or damaged, etc.

In an embodiment, the mask system may be provided with a number of different cushions, e.g., each having cushions of different styles and/or sizes (e.g., depending on patient preference and/or fit). For example, the non-face contacting side of each cushion may include a common or universal configuration for interfacing with the frame, and the face-contacting side of the cushion may include different styles and/or sizes. This provides a modular arrangement that allows the frame to be selectively (e.g., and removably) coupled to one of multiple cushion. For example, the different cushions may include different size cushions (e.g., small, medium, and large) and may include a different cushion structures.

In an embodiment, the mask system may be provided with different shrouds, e.g., each shroud having a different style and/or size (e.g., shroud with different arrangement/style of headgear connectors, shroud with forehead support, different headgear vectors, etc).

In an embodiment, the mask system may be provided with different frames, e.g., each frame having a different style and/or size (e.g., frame with different vent arrangement, small, medium, and large size frame, etc).

In an embodiment, the mask system may be provided with a number of different elbows, e.g., each having a vent arrangement, AAV (in the case of an oro-nasal mask), and/or elbow of different styles and/or sizes. In the illustrated embodiment of FIGS. **27-30**, the vent arrangement **76** and AAV **85** are structured to be removably attachable to the elbow **70**. This provides a modular arrangement that allows the elbow to be selectively and removably coupled to one of multiple vent arrangements and/or AAVs. This also allows the vent arrangement and AAV to be easily replaced, e.g., if damaged.

5.1 Shroud to Frame Connection

The shroud is mounted on the outer surface of the frame, e.g., preferably with a tight, conforming fit on the frame.

5.1.1 Upper Retaining Mechanism

In the illustrated embodiment of FIGS. **1-5**, the shroud **1020** is connected to the frame **1040** by an upper retaining mechanism or interfacing structure **1048** located on the top end of the frame and shroud.

As shown in FIGS. **2** to **5**, the upper retaining mechanism **1048** is in the form of two taper locks structured to secure the shroud **1020** on the frame **1040** and prevent unintentional disassembly particularly due to headgear forces. In this embodiment, opposing sides of the frame include a female slot **1055** adapted to receive a respective tang protrusion (which tapers along its length) on the underside of the shroud **1020**. The tapered protrusion engages within a respective female slot, e.g., with a friction fit.

FIGS. **10** to **19-4** show another embodiment of a mask system **1110** which more clearly illustrates an embodiment of the taper lock. FIGS. **10** to **17** show various views of the frame **1140**, shroud **1120**, and elbow **1170** of the mask system **1110**.

As best shown in FIGS. **11** to **13**, opposing sides of the top end of the frame **1140** include a platform **1154** which provides a first female slot **1155**(**1**). In addition, the space between the platform **1154** and the outer surface of the frame **1140** defines a second female slot **1155**(**2**). As best shown in FIG. **17**, opposing sides of the top end of the shroud **1120** include a tang protrusion **1156** on the underside of the shroud **1120**. The tang protrusion **1156** includes a first tang **1156**(**1**) and a second tang **1156**(**2**) that extends generally transverse to the first tang **1156**(**1**). As shown in FIGS. **18-1** and **18-2**, each tang may taper along its length, i.e., thinner towards its free end.

FIGS. **18-1** and **18-2** and **19-1** to **19-4** sequentially illustrate attachment of the shroud **1120** to the frame **1140**. As illustrated, the tangs **1156**(**1**), **1156**(**2**) of each tang protrusion **1156** are structured to engage with respective slots **1155**(**1**), **1155**(**2**), e.g., with a friction fit. As best shown in FIGS. **19-1** to **19-4**, each slot **1155**(**2**) includes lead-ins or guides **1157** that curve along their length (i.e., extend in vertical and horizontal direction) so as to guide the tang **1156**(**2**) into the slot **1155**(**2**) and aid assembly. FIGS. **18-2** and **19-4** show the tangs **1156**(**1**), **1156**(**2**) when fully inserted with respective slots **1155**(**1**), **1155**(**2**).

In an alternative embodiment, as shown in FIG. **20**, the upper retaining mechanism may include a clip-type arrangement. As illustrated, opposing sides of the top end of the frame **1240** provide a shoulder **1255**(**1**) and a tapered protrusion **1255**(**2**). Opposing sides of the top end of the shroud **1220** include a first tang **1256**(**1**) and a second tang **1256**(**2**) on the underside of the shroud **1220**. In use, each first tang **1256**(**1**) is engaged with the respective shoulder **1255**(**1**) and the second tang **1256**(**2**) is engaged or clipped onto the tapered protrusion **1255**(**2**), e.g., with a snap-fit.

5.1.2 Lower Retaining Mechanism

In an embodiment, the shroud may also be connected to the frame by a lower retaining mechanism located on the bottom end of the frame and shroud. For example, a retaining mechanism may be provided to the opening of the shroud which is structured to interlock or otherwise engage with the opening of the frame.

For example, as shown in FIGS. **14**, **15**, **17**, and **21**, the opening **1132** of the shroud **1120** may include structure adapted to engage the collar **1149** surrounding the frame opening **1146** with a snap-fit. As illustrated, the shroud **1120** includes snap fingers **1145**(**1**) (e.g., three snap fingers) and sandwich tabs **1145**(**2**) (e.g., three sandwich tabs) that extend from the opening **1132**. The snap fingers and sandwich tabs are alternatively spaced about the opening.

In use, the snap fingers **1145**(**1**) resiliently deflect (e.g., 0.5 mm deflection) and engage respective part-annular protrusions **1149**(**1**) provided to the collar **1149** (e.g., see FIGS. **22** and **23**) to provide an initial retention of the shroud **1120** to the frame **1140** (e.g., with allowable stresses), e.g., to facilitate assembly and disassembly. In addition, as the snap fingers

1145(1) engage respective protrusions 1149(1), the sandwich tabs 1145(2) are received in respective recesses 1149(2) provided to the end of the collar 1149 (e.g., see FIGS. 22 and 23). When the elbow 1170 is engaged with the frame 1140 (e.g., see FIG. 23), an annular protrusion 1171 on the elbow 1170 is positioned on an opposing side of the sandwich tabs 1145(2) so that the sandwich tabs 1145(2) are sandwiched between the collar 1149 and the elbow 1170. Thus, the sandwich tabs utilize elbow retention forces to retain the shroud on the frame during use. The elbow 1170 has a distal shoulder 1173 adapted to extend under the edge of the frame 1140 to retain the elbow to the frame. The snap fingers 1145(1) allow the shroud to connect to the frame independent of the elbow.

In an alternative embodiment, as shown in FIG. 24, the shroud's lower section may be structured to clip to a single point below the collar. As illustrated, the lower end of the shroud 1320 includes a snap finger 1345 that is engaged or clipped onto a protrusion 1349(1) spaced below the collar 1349 of the frame 1340, e.g., with a snap-fit. In this embodiment, the protrusion 1349 extends from the cover enclosing auxiliary ports. This arrangement may facilitate molding of the collar on the frame, e.g., uniform thickness of the collar prevents molding distortions. In addition, removal of the protrusions 1149(1)/recesses 1449(2) from the collar may reduce the risk of leak.

5.1.3 Finger Grip

In an embodiment, the outer surface of the frame 1040 may include finger grips or recessed portions 1097, which are positioned to be exposed under the shroud 1020. The finger grips are adapted to allow the patient an improved ability to grip the frame and/or shroud which is particularly useful when disengaging the shroud from the frame.

5.1.4 Alternative Interfacing Structure

In an alternative embodiment, as shown in FIG. 27-30, the shroud 20 includes an open construction that provides an annular or part annular retaining portion 22 structured to retain the frame 40 and the elbow 70. As illustrated, the annular retaining portion 22 includes an interfacing structure 23 along an inner edge that is adapted to interface with or otherwise removably connect to an interfacing structure 48 along the outer perimeter of the frame 40 (e.g., see FIG. 28). In the illustrated embodiment, the interfacing structure 23 is in the form of opposed flanges 23(1) that are adapted to interlock with respective locking structures 48(1) provided on opposing sides of the frame 40. However, other suitable arrangements for attaching the frame 40 to the shroud 20 are possible, e.g., friction fit, snap-fit, mechanical interlock, or other suitable attachment mechanism.

For example, the frame 40 may be coupled to the shroud 20 in a manner that allows the frame 40 to be locked in different angular positions with respect to the shroud 20, e.g., pivotally mounted.

5.1.5 Alternative Upper Headgear Connector

FIGS. 40-1 to 40-7 illustrate a frame and a clip-on upper headgear connector or rigidizer according to another embodiment of the present invention.

The frame 442 includes an opening 449 adapted to engage a frame shroud and/or elbow. Around and under the opening 449 is the u-shaped slot 402 for gas washout and auxiliary ports 443 on each side thereof.

In this embodiment, each upper side of the frame 442 includes a retaining member 433 and an upper intermediate portion of the frame 442 includes retaining grooves 435, which are structured and arranged to retain an upper headgear connector or rigidizer 424.

As best shown in FIGS. 40-6 and 40-7, the upper headgear connector 424 includes a pair of elongated arms or rigidizers 426 coupled by a pair of wire members 428. Each rigidizer 426 includes a slot 427 at its free end adapted to receive a respective headgear strap in use.

In use, the upper headgear connector 424 is adapted to clip onto the frame 442 (e.g., see FIGS. 40-1 and 40-2). Specifically, intermediate portions of the wire members 428 are received in respective grooves 435 of the frame 442, and end portions of the wire members 428 extend through respective retaining members 433 with the rigidizers 426 providing a shoulder to interlock with respective retaining members 433. FIGS. 40-4 and 40-5 show an upper portion of a retaining member 433 to illustrate the groove 433(1) adapted to receive a respective wire. As illustrated, the end of the groove 433(1) includes tapered side walls 433(2) and drops off towards a rear side 433(3) to position the rigidizers 426 into interlocking engagement with the retaining member 433.

FIGS. 41-1 to 41-12 illustrate an upper portion of a frame and a clip-on upper headgear connector or rigidizer according to another embodiment of the present invention.

As illustrated, the upper portion of the frame 542 includes a retaining member 533 on each side thereof and a retaining groove 535 along an intermediate portion thereof, which are structured and arranged to retain an upper headgear connector or rigidizer 524.

As best shown in FIGS. 41-5 and 41-12, the upper headgear connector 524 includes a pair of elongated arms or rigidizers 526 coupled by a connecting portion 528. Each rigidizer 526 includes a slot 527 at its free end adapted to receive a respective headgear strap in use. In addition, the upper headgear connector 524 includes a clip structure 525 on each side of the connecting portion 528.

In use, the upper headgear connector 524 is adapted to clip onto the frame 542 (e.g., see FIGS. 41-1 and 41-2). Specifically, the connecting portion 528 is received in the groove 535 of the frame 542, and the clip structures 525 releasably interlock with respective retaining members 533. As best shown in FIGS. 41-3 and 41-4, each retaining member 533 provides a cross-bar, and each clip structure 525 provides a v-shaped configuration that is adapted to resiliently deflect through the cross-bar and provide a shoulder to releasably interlock with the cross-bar.

FIGS. 42-1 to 42-7 illustrate an alternative embodiment for engaging the upper headgear connector with the frame. As illustrated, each retaining member 533 provides an open-ended cross-bar, and each clip structure 525 provides an elongated arm. In this embodiment, the cross-bar is structured to resiliently deflect to allow the clip structure 525 to extend through the cross-bar and releasably engage the cross-bar, e.g., with a friction fit. In addition, the upper headgear connector 524 of FIGS. 42-1 to 42-7 includes a c-shaped clip structure 529 adapted to interlock with a tab 549 provided to the frame 542 (see FIGS. 42-1 and 42-2).

5.1.6 Grommet Attachment

FIGS. 44 and 45 illustrate an alternative mask arrangement in which the shroud is attached to the frame via a grommet.

For example, as shown in FIG. 44, the frame 740 includes a grommet 745 (e.g., constructed of a rubber) and the shroud 720 includes an opening 725 adapted to receive the grommet 745 to secure the shroud 720 to the frame 740. As illustrated, the shroud 720 includes elongated upper and lower arms 724, 726 each with a slot 727 at its free end adapted to receive a respective headgear strap in use.

FIG. 45 illustrates an alternative shroud 820 which includes a single arm with a slot 827 at each end adapted to receive a respective headgear strap in use. In addition, the shroud 820 provides an elongated inner slot 825 adapted to receive the grommet 745 of the frame 740. The elongated slot

825 allows the grommet 745 to be fixed in one of multiple positions along the length of the slot 825, in contrast to the shroud 720 which provides a single fixed position. In an embodiment, the shroud 820 may be slidable with respect to the grommet 745 to allow an infinite number of positions with respect to the frame 740.

In each embodiment, the grommet 745 (e.g., constructed of a rubber) fixes the shroud in position but the inherent flexibility of the grommet provides a flexible connection to decouple the shroud from the frame and allow a range of movement between the two components, e.g., like a ball joint or gimbal. Such arrangement helps with fitting and sealing of the mask to the patient's face. That is, the flexible connection allows the mask to selectively adjust and/or self-fit with the patient's face.

5.2 Cushion to Frame Connection

In FIGS. 1-8, the non-face contacting side of the cushion 1060 is connected to frame 1040 in a tongue and groove relationship. The tongue 1066 (see FIGS. 1C, 1D, and 8) of the cushion 1060 is inserted within a groove 1041 (see FIGS. 1C and 1D) provided along the perimeter of the frame 1040. The tongue and groove relationship may also include a locking lip or sealing lip 1068 (see FIGS. 1C, 1D, and 8) on the cushion that is adapted to interlock with an undercut bead 1042 (see FIGS. 1C and 1D) within the frame groove to fixably retain the cushion to the frame.

In the illustrated embodiment, the cushion 1060 also includes one or more positioning features located around its circumference to assist with proper alignment of the cushion with the frame 1040. As shown in FIG. 7, the cushion 1060 includes notches and/or protrusions (e.g., two notches 1067 and one protrusion 1069) adapted to engage with complementary features in the frame, e.g., interlocking relationship.

5.2.1 Co-Molding Frame and Cushion

In an embodiment, as shown in FIGS. 27-30, the frame 40 and cushion 44 may be co-molded with one another to form a one-piece, integrated component. For example, the frame 40 may be molded of a first material adapted to interface with the shroud 20 and the cushion 44 may be co-molded onto the frame 40 of a second material adapted to interface with patient's face.

In such embodiment, the cushion 44 may be constructed of a relatively soft elastomeric material (e.g., silicone) for sealing and the frame 40 may be constructed of a more rigid material than the cushion 44 (e.g., polycarbonate, polypropylene) for interfacing with the frame.

Co-molding the frame 40 to the cushion 44 provides a chemical bond without necessarily forming a mechanical interlock. As a result, the connection includes no cracks, a gas tight seal, and clean interface. Moreover, such co-molded connection relaxes tolerances as the mold materials are sufficiently flexible to fill in any gaps at the interface between the frame 40 and the cushion 44. Also, the co-molded frame/cushion provides a reduced part count (reduced cost) and facilitates assembly/disassembly to the shroud 20.

In an alternative embodiment, as shown in FIG. 33, the frame 40 and cushion 44 may be integrally formed in one piece, e.g., of a silicone material. That is, the frame 40 may have the same shape and structure as described above, but be integrally molded of the same material, e.g., silicone.

In an embodiment, the integrally formed frame 40/cushion 44 may be co-molded to the shroud 20, e.g., constructed of polycarbonate or polypropylene. For example, the shroud 20 may be constructed of a relatively rigid material (e.g., polycarbonate or polypropylene) and the frame 40/cushion 44 may be co-molded onto the shroud 20 of a relatively soft elastomeric material (e.g., silicone).

5.3 Vent Arrangement

In FIGS. 1, 1B, 1C, 1D, and 2-5, the vent arrangement 1076 is provided to the frame and includes a plurality of holes 1077 (e.g., 5-100 holes, e.g., 20-50 holes, or about 35 holes) oriented at an angle (e.g., 45°) on the outer surface of the frame so as ensure the exhausted air is directed away from the patient and preferably their bed partner when the patient is sleeping. As shown in FIGS. 1C and 1D, each hole 1077 may include a contour or taper along its length. However, it should be appreciated that the vent arrangement may include other suitable arrangements, e.g., different number of holes, hole arrangement, positioning on frame, vent provides part pf interlocking structure with shroud, etc.

FIG. 35-1 illustrates a vent arrangement 276 provided to the frame 240 for gas washout. In the illustrated embodiment, the vent arrangement 276 is in the form of a vent insert (e.g., elastomeric vent insert) that is adapted to be removably supported within an outlet opening in the frame 240. The vent insert may be similar those described in U.S. Pat. Nos. 6,561,190, 6,561,191, and 7,207,335, each of which is incorporated herein by reference in its entirety. However, it should be appreciated that the vent arrangement may have other suitable forms (e.g., vent holes in frame 40 (FIG. 28), etc.).

FIGS. 37-3, 39-2, and 39-4 illustrate a frame 340 that includes a u-shaped slot 302 that receives a u-shaped plug-type vent 305 for gas washout. As illustrated, the plug-type vent 305 wraps around and under the opening in the frame 340 for the elbow 370. The plug-type vent 305 includes a plurality of tracks or grooves 307 on each side thereof. In use, the grooved plug-type vent 305 forms a seal with the slot 302 so that exhausted air can exit between the slot walls and the grooves 307 on the plug-type vent 305. In an embodiment, the port caps 347 may be integrated or incorporated into the plug-type vent 305 (e.g., integrally formed in one piece). Further details of such a plug-type vent arrangement are provided in U.S. patent application Ser. No. 12/230,120, filed Aug. 22, 2008, which is incorporated herein by reference in its entirety. FIGS. 39-2 to 39-6 show the frame 340 with the grooved plug-type vent 305 removed so as to more clearly illustrate the u-shaped slot 302 and auxiliary ports 343 on each side thereof.

Also, it should be appreciated that the vent arrangement may be provided to the elbow. For example, a shown in FIGS. 27-30, the vent arrangement 76 is in the form of a vent insert that is adapted to be removably supported within an outlet opening in the elbow 70. In an embodiment, the vent arrangement 76 includes a base adapted to be supported within the outlet opening, one or more grill components or media (e.g., filter, membrane, or other porous material) provided to the base and structured to diffuse vent flow, and a cover to maintain the grill components/media within the base. Only the cover 77 of the vent arrangement 76 is visible in FIGS. 27-30.

Exemplary embodiments of such a vent arrangement are disclosed in U.S. patent application Ser. No. 12/230,120, filed Aug. 22, 2008, which is incorporated herein by reference in its entirety.

However, it should be appreciated that the vent arrangement may include other suitable arrangements, e.g., vent insert with one or more vent holes.

Also, the elbow may provide an alternative venting arrangement to the vent insert. For example, as indicated in dashed lines in FIG. 30, the first end portion 74(1) of the elbow 70 (e.g., along the interfacing structure 75) may include one or more vent holes 276 for gas washout. The one or more holes 276 may be provided to a soft part (e.g., silicone seal as described below) and/or a hard part (e.g., polycarbonate, polypropylene) of the elbow. The holes 276 may extend

around the entire perimeter of the first end portion **74**(**1**) or may extend along one or more portions of the first end portion **74**(**1**). It is noted that providing vent holes along the entire perimeter of the elbow may help to disperse the vent flow in use. However, other suitable hole arrangements, hole numbers, and/or hole shapes along the first end portion **74**(**1**) and/or other portions of the elbow are possible.

5.4 Ports

In FIGS. **1**-**5**, the base of the frame **1040** includes two ports **1043** positioned so that in use, oxygen or other breathable gas can be delivered close to the patient's nares or pressure monitoring equipment can be attached. The ports **1043** may also be used to attach additional medical equipment such as pressure or flow sensors. The ports may be selectively closable or sealable by a ports cap.

In an alternative embodiment, as shown in FIGS. **25** and **26**, the frame **1040** may include a side port **1043**.**1**, e.g., in addition to or as an alternative to the ports **1043**.

FIGS. **35**-**1** and **35**-**2** show a frame **240** that includes an auxiliary port or spigot **243** on an upper portion of the frame, e.g., for supplemental oxygen, measurement device, etc.

In FIGS. **37**-**1** to **37**-**3** and **39**-**1** to **39**-**6**, the frame **340** includes an auxiliary port or spigot **343** on each side thereof, e.g., for supplemental oxygen, measurement device, etc. Port caps **347** are provided to seal respective ports **343**.

6. Interface Seal

In an embodiment, a seal may be provided at the interface between the elbow and the shroud, at the interface between the frame and the shroud, and/or at the interface between the elbow and the frame. For example, a seal (e.g., elastomeric, ring-shaped seal) may be formed separately from the modules and attached at the interface (e.g., sandwiched between modules, adhesive, etc.). Alternatively, a seal may be co-molded with one or more of the modules. In an embodiment, a silicone lip seal may be provided to the frame to seal against the elbow, thereby reducing leak.

In another embodiment, as shown in FIG. **27**-**30**, the interfacing structure **75** of the elbow **70** may be constructed of a relatively soft, sealing material (e.g., silicone, which may be co-molded to the harder material of the elbow) that is structured to provide a seal at the interface between the elbow **70** and the shroud **20**. Also, the relatively soft interfacing structure **75** (e.g., silicone) provides a "soft" attachment to the relatively hard shroud **20** (e.g., polycarbonate, polypropylene) which may allow an interference type fit. As noted above, one or more vent holes may be provided to the softer interfacing structure and/or the harder elbow.

While the invention has been described in connection with what are presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments, but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the invention. Also, the various embodiments described above may be implemented in conjunction with other embodiments, e.g., aspects of one embodiment may be combined with aspects of another embodiment to realize yet other embodiments. Further, each independent feature or component of any given assembly may constitute an additional embodiment. Furthermore, each individual component of any given assembly, one or more portions of an individual component of any given assembly, and various combinations of components from one or more embodiments may include one or more ornamental design features. In addition, while the invention has particular application to patients who suffer from OSA, it is to be appreciated that patients who suffer from other illnesses (e.g., congestive heart failure, diabetes, morbid obesity, stroke, bariatric surgery, etc.) can derive benefit from the above teachings. Moreover, the above teachings have applicability with patients and non-patients alike in non-medical applications.

What is claimed is:

1. A mask system, comprising:

(i) a shroud module; wherein the shroud module includes headgear connectors adapted to removably attach to respective headgear straps of headgear; and

(ii) a cushion module, comprising:

a rigid or semi-rigid frame defining a breathing chamber; and

a cushion to form a seal with the patient's face in a nasal bridge region, a cheek region and a lower lip/chin region of the patient's face,

wherein the cushion is constructed of a first, relatively soft, elastomeric material and the frame is constructed of a second material that is more rigid than the cushion,

wherein the shroud module and the cushion module are configured to be removably and non-rotatably coupleable to one another; and

wherein the frame includes a protruding vent arrangement having a plurality of holes, wherein the shroud module includes a first opening to accommodate said protruding vent arrangement, and further wherein the shroud module includes a second opening positioned to align with a frame opening of the frame leading to the breathing chamber.

2. The mask system of claim **1** wherein the cushion comprises one or more folds in a lower lip/chin region of the cushion.

3. The mask system of claim **2**, wherein a nasal bridge portion of the cushion includes one or more folds to provide in use a higher level of adaptability or flexibility to the nasal bridge region of the cushion module relative to another region of the cushion module;

and further wherein the one or more folds in the nasal bridge region has a relatively high degree of flexibility and the one or more folds in the lower lip/chin region has a relatively low degree of flexibility.

4. The mask system of claim **1**, wherein a nasal bridge portion of the cushion includes one or more folds to provide in use a higher level of adaptability or flexibility to the nasal bridge region of the cushion module relative to another region of the cushion module;

and further wherein each of said one or more folds comprises adjacent first side walls interconnected by a second side wall.

5. The mask system of claim **1**, wherein the frame includes a collar surrounding said frame opening, and wherein the shroud includes a retaining portion with a plurality snap fingers structured to engage the collar with a snap-fit.

6. The mask system of claim **1**, wherein the shroud module includes upper and lower headgear connectors on each side of the shroud module.

7. The mask system of claim **6**, wherein each upper headgear connector includes a slot adapted to receive a respective headgear strap in use.

8. The mask system of claim **7**, wherein each lower headgear connector is adapted to be removably interlocked with a headgear clip associated with a respective headgear strap.

9. The mask system of claim **6**, wherein the upper headgear connectors and the lower headgear connectors define a fulcrum point or moment of pivoting that is positioned between the upper headgear connectors and the lower headgear connectors.

10. The mask system of claim 1, wherein the shroud module includes an annular or part annular cushion retaining portion structured to retain the cushion module.

11. The mask system of claim 1, further comprising an elbow module adapted to be connected to an air delivery tube that delivers breathable gas to the patient.

12. The mask system of claim 11, wherein the elbow module is provided to the shroud module.

13. The mask system of claim 11, wherein the elbow module comprises polycarbonate.

14. The mask system of claim 11, wherein the elbow module and the shroud module are directly connected with a mechanical interlock while allowing 360 degree rotation of the elbow module.

15. The mask system of claim 11, wherein the elbow module includes an anti-asphyxia valve and wherein the anti-asphyxia valve includes a flap portion adapted to selectively close a port provided in the elbow module.

16. The mask system of claim 1, wherein the cushion module includes at least first and second cushion modules adapted to be provided to the shroud module, said at least first and second cushion modules being different from one another in at least one aspect.

17. The mask system of claim 1 comprising a small cushion module, a medium cushion module and a large cushion module, wherein each of said small cushion module, said medium cushion module and said large cushion module is removably coupleable to the same shroud module.

18. The mask system of claim 1, wherein the shroud module and the frame comprise polycarbonate and the cushion comprises silicone.

19. The mask system of claim 1, wherein:

the headgear includes a pair of upper straps and a pair of lower straps, with the upper straps being removably attached to respective ones of the headgear connectors and the lower straps being connected to respective ones of the headgear connectors,

a free end of each of the upper straps and the lower straps includes a hook tab structured to engage a remainder of the respective upper strap and respective lower strap to secure the upper and lower straps in place in a length adjustable manner,

the upper straps split to form a pair of top straps and a pair of rear straps, the top straps being connected together by a buckle and configured to pass over the top of the patient's head in use, the rear straps being adapted to pass behind the patient's head in use, and

a free end of each of the top straps has a hook tab threaded through the buckle to engage a remainder of the respective top strap to secure the top straps in place relative to the buckle in a length adjustable manner.

20. The mask system of claim 19, wherein the upper straps provide padding to the respective headgear connectors of the shroud module on the patient's face in use.

21. The mask system of claim 19, wherein the rear straps and the top straps form a closed loop to encircle a rear portion of the patient's head when in use.

22. The mask system of claim 19, wherein the frame includes a frame opening leading to the breathing chamber, and wherein the front opening of the shroud module and the frame opening of the frame are aligned along a common longitudinal axis, and wherein the shroud module and the cushion module are removably snap-fit attached to one another by moving the shroud module and the cushion module towards one another along the longitudinal axis.

23. The mask system of claim 22, wherein the headgear connectors are configured and arranged to allow pivoting of the cushion module, when attached with the shroud module, about a fulcrum point or moment of pivoting that is positioned between the upper connectors and the lower connectors.

24. The mask system of claim 23, wherein the frame is rigid.

25. The mask system of claim 19, wherein the frame is rigid.

26. The mask system of claim 1, wherein the second opening of the shroud module and the frame opening of the frame are aligned along a common longitudinal axis, and wherein the mask system further comprises a snap-fit arrangement to removably snap-fit attach the shroud module and the cushion module to one another by moving the shroud module and the cushion module towards one another along the longitudinal axis.

27. The mask system of claim 26, wherein the headgear connectors are configured and arranged to allow pivoting of the cushion module, when attached with the shroud module, about a fulcrum point or moment of pivoting that is positioned between the upper connectors and the lower connectors.

28. The mask system of claim 1, wherein:

the frame includes a collar surrounding said frame opening, and wherein the shroud includes a retaining portion with at least one snap finger structured to engage the collar with a snap-fit,

the shroud module includes upper and lower headgear connectors on each side of the shroud module,

each upper headgear connector includes a slot adapted to receive a respective headgear strap in use,

each lower headgear connector is adapted to be removably interlocked with a headgear clip associated with a respective headgear strap,

the mask assembly further comprises an elbow module adapted to be connected to an air delivery tube that delivers breathable gas to the patient, and

the elbow module is rotatably attached to the shroud module while allowing 360 degree rotation of the elbow module.

29. The mask system of claim 28, wherein each of the shroud module and the frame comprises polycarbonate, and the cushion comprises silicone.

30. The mask system of claim 28, wherein the frame is rigid.

31. The mask system of claim 1, wherein the frame is rigid.

32. A system for treating a patient with sleep disordered breathing, comprising:

the mask system of claim 1;

a flow generator to generate a supply of air at positive pressure to be delivered to the mask system; and

an air delivery tube configured to deliver the supply of air from the flow generator to the mask system.

33. A mask system, comprising:

(i) a shroud module; wherein the shroud module includes headgear connectors adapted to removably attach to respective headgear straps of headgear; and

(ii) a cushion module, comprising:

a frame defining a breathing chamber; and

a cushion to form a seal with the patient's face in at least a nasal bridge region and a cheek region of the patient's face,

wherein the cushion is constructed of a first, relatively soft, elastomeric material and the frame is constructed of a second material that is more rigid than the cushion, and a nasal bridge portion of the cushion includes one or more folds to provide in use a higher level of

adaptability or flexibility to the nasal bridge region of the cushion module relative to another region of the cushion module;

wherein the shroud module and the cushion module are configured to be removably coupleable to one another, and

wherein the shroud module includes a front opening of substantively circular shape and a retaining portion extending rearwardly from the front opening, towards the frame, and structured to snap-fit with the cushion module.

34. The mask system of claim **33**, further comprising an elbow module directly mechanically interlocked with the shroud module while allowing 360 degree rotation of the elbow module.

35. The mask system of claim **33**, wherein the shroud module includes upper and lower headgear connectors on each side of the shroud module;

wherein each upper headgear connector includes a slot adapted to receive a respective headgear strap in use; and

wherein each lower headgear connector is adapted to be removably interlocked with a headgear clip associated with a respective headgear strap.

36. The mask system of claim **33**, further comprising an elbow module adapted to be connected to an air delivery tube that delivers breathable gas to the patient, wherein the shroud module is structured to directly retain and carry the elbow module.

37. The mask system of claim **33**, wherein the frame includes a frame opening leading to the breathing chamber, and wherein the front opening of the shroud module and the frame opening of the frame are aligned along a common longitudinal axis, and wherein the shroud module and the cushion module are removably snap-fit attached to one another by moving the shroud module and the cushion module towards one another along the longitudinal axis.

38. The mask system of claim **37**, wherein the headgear connectors are configured and arranged to allow pivoting of the cushion module, when attached with the shroud module, about a fulcrum point or moment of pivoting that is positioned between the upper connectors and the lower connectors.

39. The mask system of claim **38**, wherein the frame is rigid.

40. The mask system of claim **33**, wherein the frame is semi-rigid or rigid.

41. The mask system of claim **40**, wherein the frame is rigid.

42. A system for treating a patient with sleep disordered breathing, comprising:

the mask system of claim **33**;

a flow generator to generate a supply of air at positive pressure to be delivered to the mask system; and

an air delivery tube configured to deliver the supply of air from the flow generator to the mask system.

43. A mask system for delivery of a supply of air at positive pressure to a patient's airway, the mask system comprising:

a cushion module comprising a frame defining a breathing chamber configured to receive the positive pressure air, and a cushion to form a seal with the patient's face in a nasal bridge region, a cheek region and a lower lip/chin region of the patient's face, wherein the cushion is constructed of a first, relatively soft, elastomeric material and the frame is constructed of a second material that is more rigid than the cushion, the frame including a washout vent, the frame including an opening;

headgear to maintain the mask system in a desired position on the patient's face, the headgear comprising a pair of upper headgear straps each configured to extend above a respective one of the patient's ears in use and a pair of lower headgear straps each configured to extend below a respective one of the patient's ears in use, wherein a free end of each of the upper headgear straps and the lower headgear straps includes a hook tab structured to engage a remainder of the respective upper headgear strap and respective lower headgear strap to secure the upper and lower straps in place in a length adjustable manner, wherein the headgear includes a pair of top straps and a pair of rear straps, each said top strap being configured to extend from generally above a respective ear of the patient such that the top straps cross over the top of the patient's head in use, the rear straps being adapted to pass behind the patient's head in use, and wherein the rear straps and the top straps together at least partly form a closed loop to encircle a rear portion of the patient's head when in use;

a shroud module including headgear connectors adapted to removably attach to the headgear, wherein the headgear connectors include two upper connectors associated with the upper headgear straps, the shroud module having an opening of circular shape, and two lower connectors associated with the lower headgear straps, each said upper headgear connector including a slot or receiving hole adapted to receive one of the upper headgear straps, wherein the shroud module and the frame of the cushion module are configured to be removably snap-fit attached to one another in a non-rotatable manner by pushing the shroud module towards the frame along a longitudinal axis of both the opening of the frame and the opening of the shroud; and

an elbow rotatably attached to and carried by the shroud module or the frame of the cushion module, the elbow being configured to deliver the positive pressure air to the breathing chamber, the elbow including a swivel adapted to connect to an air delivery tube, the elbow including an anti-asphyxia valve (AAV) and a port that is selectively closed by a flap portion of the AAV.

44. The mask system of claim **43**, wherein:

each upper headgear connector includes a laterally elongated arm and the slot or receiving hole is positioned at a free end of the arm,

each arm is contoured to extend along the patient's cheek, curving below the patient's field of vision or eyes, and then curves upwards at an angle relative to a horizontal axis in use,

the arms are at least semi-rigid to help prevent up and down movement of the arms relative to the face of the patient,

the top straps are integral with one another,

the frame, the shroud module and the headgear are structured to control rotation of the mask system in the sagittal and coronal planes of the patient in use, without a forehead support, and

the elbow is rotatably snap-fit to the frame of the cushion module.

45. The mask system of claim **43**, wherein:

each upper headgear connector includes a laterally extending arm and the slot or receiving hole is positioned at a free end of the arm,

the arms are at least semi-rigid to help prevent up and down movement of the arms relative to the face of the patient,

the elbow is rotatably snap-fit to the frame of the cushion module,

the top straps are integral with one another, and

the frame includes a co-molded ring-shaped lip seal to seal against the elbow when connected.

46. The mask system of claim 43, wherein:
the elbow is rotatably attached the shroud module,
the upper headgear straps provide padding to the respective headgear connectors of the shroud on the patient's face in use,
the frame includes a protruding vent arrangement having a plurality of holes, wherein the shroud module includes a first opening to accommodate said protruding vent arrangement, further wherein the shroud module includes a second opening to accommodate the elbow,
the frame includes an opening and the frame further includes a collar surrounding said opening, and wherein the shroud module includes a retaining portion with one or more rearward extending snap fingers structured to engage the collar with a snap-fit, and
the top straps are connected together with a buckle allowing independent adjustment of each of the top straps.

47. The mask system of claim 43, wherein the mask system is configured and arranged to pivot about a fulcrum point or moment of pivoting that is positioned between the upper connectors and the lower connectors.

48. The mask system of claim 43, wherein the frame is semi-rigid or rigid.

49. The mask system of claim 48, wherein the frame is rigid.

50. A system for treating a patient with sleep disordered breathing, comprising:
the mask system of claim 43; and
a flow generator to generate a supply of air at positive pressure to be delivered to the mask system, wherein
the air delivery tube is configured to deliver the supply of air from the flow generator to the mask system.

51. A mask system for delivery of a supply of air at positive pressure to a patient's airway, the mask system comprising:
a cushion module comprising a frame defining a breathing chamber configured to receive the positive pressure air, and a cushion to form a seal with the patient's face in a nasal bridge region, a cheek region and a lower lip/chin region of the patient's face, wherein the cushion is constructed of a first, relatively soft, elastomeric material and the frame is constructed of a second material that is more rigid than the cushion, the frame including a washout vent;
headgear to maintain the mask system in a desired position on the patient's face, the headgear comprising a pair of upper headgear straps each configured to extend above a respective one of the patient's ears in use and a pair of lower headgear straps each configured to extend below a respective one of the patient's ears in use, wherein a free end of each of the upper headgear straps and the lower headgear straps includes a hook tab structured to engage a remainder of the respective upper headgear strap and respective lower headgear strap to secure the upper and lower straps in place in a length adjustable manner, wherein the headgear includes a pair of top straps and a pair of rear straps, each said top strap being configured to extend from generally above a respective ear of the patient such that the top straps cross over the top of the patient's head in use, the rear straps being adapted to pass behind the patient's head in use, and wherein the rear straps and the top straps together at least partly form a closed loop to encircle a rear portion of the patient's head when in use;
a shroud module including headgear connectors adapted to removably attach to the headgear, wherein the headgear connectors include two upper connectors associated with the upper headgear straps and two lower connectors associated with the lower headgear straps, each said upper headgear connector including a slot or receiving hole adapted to receive one of the upper headgear straps, wherein the shroud module and the frame of the cushion module are configured to be removably snap-fit attached to one another in a non-rotatable manner; and
an elbow rotatably attached to and carried by the shroud module or the frame of the cushion module, the elbow being configured to deliver the positive pressure air to the breathing chamber, the elbow including a swivel adapted to connect to an air delivery tube, the elbow including an anti-asphyxia valve (AAV) and a port that is selectively closed by a flap portion of the AAV;
the elbow is rotatably attached the shroud module,
the upper headgear straps provide padding to the respective headgear connectors of the shroud on the patient's face in use,
the frame includes a protruding vent arrangement having a plurality of holes, wherein the shroud module includes a first opening to accommodate said protruding vent arrangement, further wherein the shroud module includes a second opening to accommodate the elbow,
the frame includes a frame opening and the frame further includes a collar surrounding said frame opening, and wherein the shroud module includes a retaining portion with one or more rearward extending snap fingers structured to engage the collar with a snap-fit, and
the top straps are connected together with a buckle allowing independent adjustment of each of the top straps.

52. The mask system of claim 51, wherein the mask system is adapted to pivot about a fulcrum point or moment of pivoting that is positioned between the upper connectors and the lower connectors.

53. The mask system of claim 51, wherein the second shroud opening and the frame opening are aligned along a common longitudinal axis, and wherein the shroud and the frame are removably snap-fit attached to one another by moving the shroud and the frame towards one another along the longitudinal axis.

54. The mask system of claim 51, wherein the frame is semi-rigid or rigid.

55. The mask system of claim 54, wherein the frame is rigid.

56. A system for treating a patient with sleep disordered breathing, comprising:
the mask system of claim 51; and
a flow generator to generate a supply of air at positive pressure to be delivered to the mask system, wherein
the air delivery tube is configured to deliver the supply of air from the flow generator to the mask system.

57. A mask system for treating a patient with sleep disordered breathing with a supply of air at positive pressure, comprising:
headgear including headgear straps;
a shroud module having a pair of upper headgear connectors and a pair of lower headgear connectors adapted to removably attach to the respective headgear straps of the headgear, the shroud module having a front opening;
a rotatable elbow directly attached to the shroud; and
a cushion module, the cushion module comprising a frame defining a breathing chamber, the frame having a frame opening leading to the breathing chamber; and a cushion to form a seal with the patient's face, wherein the cushion comprises a first, relatively soft, elastomeric material and the frame comprises a second material that is more rigid than the cushion;

wherein:

the front opening of the shroud module and the frame opening of the frame are aligned along a common longitudinal axis, and wherein the shroud module and the cushion module are structured and arranged to be removably snap-fit attached to one another by moving the shroud module and the cushion module towards one another along the longitudinal axis, and

the shroud module includes a retaining portion positioned rearwardly of the front opening, towards the frame, and structured to snap fit with the cushion module.

58. The mask system of claim **57**, wherein the shroud module and the cushion module are structured and arranged to be detached from one another by moving the shroud module and the cushion module away from one another along the longitudinal axis.

59. The mask system of claim **57**, wherein the upper and lower headgear connectors are configured and arranged to allow pivoting of the cushion module, when attached with the shroud module, about a fulcrum point or moment of pivoting that is positioned between the upper headgear connectors and the lower headgear connectors.

60. The mask system of claim **57**, wherein each upper headgear connector includes a slot adapted to receive a respective headgear strap in use; and

wherein each lower headgear connector is adapted to be removably interlocked with a headgear clip associated with a respective headgear strap.

61. The mask system of claim **57**, wherein the elbow is adapted to be connected to an air delivery tube that delivers breathable gas to the patient.

62. The mask system of claim **57**, wherein:

the headgear includes upper straps and lower straps,

a free end of each of the upper straps and the lower straps includes a hook tab structured to engage a remainder of the respective upper strap and respective lower strap to secure the upper and lower straps in place in a length adjustable manner,

the upper straps split to form a pair of top straps and a pair of rear straps, the top straps being connected together by a buckle and configured to pass over the top of the patient's head in use, the rear straps being adapted to pass behind the patient's head in use, and

a free end of each of the top straps has a hook tab threaded through the buckle to engage a remainder of the respective top strap to secure the top straps in place relative to the buckle in a length adjustable manner.

63. The mask system of claim **62**, wherein the upper straps provide padding to the respective headgear connectors of the shroud module on the patient's face in use.

64. The mask system of claim **62**, wherein the rear straps and the top straps form a closed loop to encircle a rear portion of the patient's head when in use.

65. The mask system of claim **57**, wherein the frame includes a protruding vent arrangement having a plurality of gas washout holes, wherein the shroud module includes an upper opening to accommodate said protruding vent arrangement.

66. The mask system of claim **57**, wherein the cushion comprises one or more folds in a lower lip/chin region of the cushion.

67. The mask system of claim **66**, wherein a nasal bridge portion of the cushion includes one or more folds to provide in use a higher level of adaptability or flexibility to the nasal bridge region of the cushion module relative to another region of the cushion module;

and further wherein the one or more folds in the nasal bridge region has a relatively high degree of flexibility and the one or more folds in the lower lip/chin region has a relatively low degree of flexibility.

68. The mask system of claim **57**, wherein a nasal bridge portion of the cushion includes one or more folds to provide in use a higher level of adaptability or flexibility to the nasal bridge region of the cushion module relative to another region of the cushion module;

and further wherein each of said one or more folds comprises adjacent first side walls interconnected by a second side wall.

69. The mask system of claim **57**, wherein the frame includes a collar surrounding said frame opening, and wherein the retaining portion of the shroud includes a plurality of snap fingers structured to engage the collar with a snap-fit.

70. The mask system of claim **57**, wherein the elbow includes an anti-asphyxia valve and wherein the anti-asphyxia valve includes a flap portion adapted to selectively close a port provided in the elbow.

71. The mask system of claim **57**, wherein each of the shroud module and the frame comprises polycarbonate and the cushion comprises silicone.

72. The mask system of claim **57**, wherein:

the shroud module and the cushion module are structured and arranged to be detached from one another by moving the shroud module and the cushion module away from one another along the longitudinal axis,

wherein each upper headgear connector includes a slot adapted to receive a respective headgear strap in use, and wherein each lower headgear connector is adapted to be removably interlocked with a headgear clip associated with a respective headgear strap,

the elbow is adapted to be connected to an air delivery tube that delivers breathable gas to the patient,

the headgear includes upper straps and lower straps, a free end of each of the upper straps and the lower straps includes a hook tab structured to engage a remainder of the respective upper strap and respective lower strap to secure the upper and lower straps in place in a length adjustable manner, the upper straps split to form a pair of top straps and a pair of rear straps, the top straps being connected together by a buckle and configured to pass over the top of the patient's head in use, the rear straps being adapted to pass behind the patient's head in use, and a free end of each of the top straps has a hook tab threaded through the buckle to engage a remainder of the respective top strap to secure the top straps in place relative to the buckle in a length adjustable manner,

the upper straps provide padding to the respective headgear connectors of the shroud module on the patient's face in use,

the rear straps and the top straps form a closed loop to encircle a rear portion of the patient's head when in use,

the frame includes a protruding vent arrangement having a plurality of gas washout holes, wherein the shroud module includes an upper opening to accommodate said protruding vent arrangement,

the cushion comprises one or more folds in a lower lip/chin region of the cushion,

a nasal bridge portion of the cushion includes one or more folds to provide in use a higher level of adaptability or flexibility to the nasal bridge region of the cushion module relative to another region of the cushion module,

the frame includes a collar surrounding said frame opening, and wherein the retaining portion of the shroud includes a plurality of snap fingers structured to engage the collar with a snap-fit,

each of the shroud module and the frame comprises polycarbonate and the cushion comprises silicone.

73. The mask system of claim **72**, wherein the upper and lower headgear connectors are configured and arranged to allow pivoting of the cushion module, when attached with the shroud module, about a fulcrum point or moment of pivoting that is positioned between the upper headgear connectors and the lower headgear connectors.

74. The mask system of claim **72**, wherein the elbow includes an anti-asphyxia valve and wherein the anti-asphyxia valve includes a flap portion adapted to selectively close a port provided in the elbow.

75. The mask system of claim **72**, wherein the frame is semi-rigid or rigid.

76. The mask system of claim **75**, wherein the frame is rigid.

77. The mask system of claim **57**, wherein the frame is semi-rigid or rigid.

78. The mask system of claim **77**, wherein the frame is rigid.

79. A system for treating a patient with sleep disordered breathing, comprising:

the mask system of claim **57**;

a flow generator to generate a supply of air at positive pressure to be delivered to the mask system; and

an air delivery tube configured to deliver the supply of air from the flow generator to the mask system.

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